

CRACKS IN THE SYSTEM—AN EXAMINATION OF ONE TUBERCULOSIS PATIENT'S INTERNATIONAL PUBLIC HEALTH THREAT

HEARING BEFORE A SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS UNITED STATES SENATE ONE HUNDRED TENTH CONGRESS FIRST SESSION

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CONTENTS

	Page
Opening statement of Senator Tom Harkin	1
Opening statement of Senator Arlen Specter	3
Statement of Julie Gerberding, M.D., M.P.H., Director, Centers for Disease Control and Prevention, Department of Health and Human Services	4
Prepared statement	11
Statement of Deborah J. Spero, Deputy Commissioner, United States Cus- toms and Border Protection, Department of Homeland Security	17
Prepared statement	19
Statement of Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services	22
Statement of Senator Sherrod Brown	35
Statement of Andrew Speaker, Speaker Law Firm, Atlanta, Georgia	42
Statement of Steven Katkowsky, M.D., director, Department of Health and Wellness, Fulton County, Georgia	45
Statement of Nils Daulaire, M.D., M.P.H., president and chief executive offi- cer, Global Health Council	48
Prepared statement	50

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WEDNESDAY, JUNE 6, 2007

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN
SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:48 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.
Present: Senators Harkin, Specter, Cochran, and Gregg.
Also present: Senator Brown.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Before we proceed, we're trying to get a witness who could not be here, to be here, at least telephonically. We had hoped to have it visually also, but there seems to be some problems at National Jewish Hospital hooking us up. But we're going to have Mr. Speaker, I hope, telephonically here momentarily. I just want to make sure that we have him so that he can hear the proceedings as we proceed, because Mr. Speaker will be on our second panel.

Hello; is this Mr. Speaker? This is Senator Harkin in Washington. Can you hear us?

Mr. SPEAKER [by telephone]. Say it again?

Senator HARKIN. Mr. Speaker, this is Senator Harkin, chairman of the subcommittee. We are just—I just called the meeting to order. I just want to make sure that you could hear the proceedings. Are you hearing the proceedings now? Can you hear me?

Mr. SPEAKER. Yes. What is this meeting for?

Senator HARKIN. What did he say?

Mr. SPEAKER. What is this meeting for?

Senator HARKIN. I'm sorry. This is the Subcommittee on Labor-HHS that has jurisdiction over NIH and the Centers for Disease Control. This hearing is to basically look into the circumstances surrounding the events of the last few weeks concerning your case and what needs to be done to ensure that things like this don't happen in the future. That's the subject of this hearing.

We had hoped to have you hooked up visually, but there seem to be some problems in Colorado with that. But we have you telephonically. So I just ask you to listen to the proceedings, and then we have one panel. I will lay that out for you. You'll hear that. Then you'll be our witness on the second panel.

Do you understand that?

[No response.]

Well, while they're trying to get the bugs worked out of this: I'm sure everyone has heard now about the case of Andrew Speaker, the person who we just heard briefly on the phone, who was diagnosed with an active drug-resistant form of tuberculosis. On May 10, Mr. Speaker flew from Atlanta on a 12-day international odyssey, which he continued despite warnings from the Centers for Disease Control and Prevention. Then he reentered the United States at the Canadian border when a Customs agent allowed him to pass, despite knowing that Mr. Speaker was being sought by health authorities. During this hearing we'll hear testimony from Mr. Speaker by live hookup. At least I hope we will.

Obviously, this case raises grave questions on how prepared we are as a Nation to prevent the spread of a dangerous infectious disease. This subcommittee, under the leadership of Senator Specter and myself, has made it one of its top priorities, if not the top priority, to make sure that our public health infrastructure is adequately funded to respond to natural or man-made biological threats. We have provided funds for disease surveillance here and abroad. We have invested in the Centers for Disease Control and Prevention and our State and local public health systems. We have funded research in vaccine development. We have Dr. Fauci here to speak about that. We have held hearings on bioterrorism and on pandemic flu, numerous hearings, under the leadership of Senator Specter.

We did this because we know that public health, both on the Federal and local levels, is our first line of defense against new and existing infectious diseases. We did this because we knew the threats we face from both bioterrorism and emerging infectious diseases, for example SARS or pandemic flu. In the case of pandemic flu, we know that we have to count on public health because with an outbreak we will have to wait perhaps months before we have an adequate vaccine after an outbreak.

That's why I'm dismayed and concerned that so many things went wrong in this case of a drug-resistant tuberculosis. This is not the first and will not be the last time that we count on our public health system to keep us safe.

Some things went right. The doctor who first diagnosed the TB in the Atlanta man did indeed report the case to the local health department. The local health department did respond and either suggested or directed—I don't know which—that the patient not travel overseas.

But then the records kind of get confused and a little less clear. Clearly there are some gaps in planning on how to control the travel of persons with dangerous infectious diseases. It's as though the issue had not been raised before. We'll get into that with Dr. Gerberding.

We're told that there were legal issues to resolve. Well, we need to know what those are, but it seems to me that sound planning calls for resolving those issues in advance. That's where I really want to kind of guide and direct this hearing as to what happened in the planning to take care of a case like this.

The purpose of this hearing again is to learn more about what happened and, more importantly, to learn what's being done to prevent something like this from happening again. Bear in mind that an incident like this could have happened on a cruise ship, a train, commuter subways, wherever. We need to be planning for these kinds of possibilities and we need to test those plans, to test them to see if they'll work in the real world.

So this hearing will give us an opportunity to learn more about also the growing problem of drug-resistant tuberculosis and other drug-resistant infectious diseases, what's being done and should be done to address those threats. That's where we'll get with Dr. Fauci on those.

With that, I'd yield to my colleague and again person who has led this committee for so many years in making sure that we had funding for CDC that we have funding for NIH, to make sure that we're able to address these issues if and when they arise. So I'll yield to my good friend Senator Specter.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Thank you, Mr. Chairman. I commend you for this prompt hearing on this very important subject. There is world-wide concern about what has happened with this incident involving Mr. Andrew Speaker and his worldwide travels to marry and honeymoon. When you have the World Health Organization criticizing the United States Centers for Disease Control, it raises very, very important questions which we have to determine precisely what Andrew Speaker was told, by whom.

There is an apparent conflict between what the doctors say and what Mr. Speaker says. The doctors say, reportedly, that he was warned that he ought not to travel and that he would place himself at risk and many, many other people substantially at risk. He was told, according to what he has to say, that they're technically required to advise him, in effect it was really up to him, they had discharged their duties. Well, if that is so that's a very serious dereliction.

But that's what we have to make a determination of, as to who said what to whom when and what the emphasis was, and who's responsible for this international incident. Then, as Senator Harkin correctly states, the issue is where do we go from here, how do we prevent such a recurrence, how do we assure the World Health Organization and the people in other countries, those who travel on U.S. planes, that they're not at risk, that we have some sensible way for making a determination as to who is contagious and to what extent.

I thank you, Senator Harkin, for summarizing what this committee has done. I don't think any subcommittee has been more diligent about health issues than this committee. This room has been the situs since December 1998, just 10 days after we found out about embryonic stem cells, to hold 20 hearings. This subcommittee has taken the lead in taking a look at the building facilities at the Centers for Disease Control in 1999, found them in a shambles, and found \$1.5 billion to reconstruct the CDC, to say nothing of your leadership last year on initiating \$7 billion for fighting the risk of pandemic flu.

So in essence, Dr. Gerberding, Dr. Fauci, Ms. Spero, we want something for our money. It has been a lot of money and we expect some high-level performance. Everything that I have seen of CDC has done that. But now we have a serious issue which has been raised here.

I'm going to have to excuse myself. We are on the immigration bill. It's all over the front pages, and the majority leader has threatened to take the bill down unless cloture is invoked, something you don't want to hear about, and unless we dispose of a great many amendments. We started this morning at 8:30 to set a schedule and we have a long list of amendments, and my presence is required there. But I will do my best to come back. I've had some experience in questioning witnesses and I'd like to see what Mr. Speaker has to say firsthand.

So thank you again, Senator Harkin.

Senator HARKIN. Thank you very much, Senator Specter.

I will say that one other facet that I didn't mention is how this person slipped through the border, even the alert had gone out and everything, and that's why Ms. Spero is here. We want to find out, again, what do we need to do? How did this happen and what do we need to do, again, to make sure that people who are identified like that can't just come across the border like he did. So that's the reason that Ms. Spero is here, to respond to that.

So we'll open the hearing with Dr. Gerberding. Dr. Gerberding, no stranger to this subcommittee, Director of the Centers for Disease Control and Prevention. Dr. Gerberding has been a great leader, I would say this for the public record, of the Centers for Disease Control and Prevention and in guiding it through a huge building phase and again has worked very closely with this subcommittee in helping us to know where to put the money for surveillance and early detection, and especially ramping up for the possibility of pandemic flu.

So Ms. Gerberding, Dr. Gerberding, we welcome you again to the subcommittee. Normally we have a 5-minute rule, but I will waive that and go ahead and leave the record open for any other opening statements that people have. But go ahead and take whatever time necessary. At around 10 minutes we may start to get a little nervous, but if you have to take that time go ahead. Again, welcome, and please proceed.

STATEMENT OF JULIE GERBERDING, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. GERBERDING. Thank you, so much, Senator. I do want to acknowledge the statements made by both you and Senator Specter. This committee truly has been incredibly supportive and interested in protecting the health of our Nation and really people around the world, and I think Dr. Fauci and I will both agree that we are very fortunate to have that kind of support for our agencies.

What I'd like to do very quickly is to talk about what should have happened in this situation, what actually did happen in this situation, and what do we need to change to make sure that the problems that occurred don't happen again. So I'm actually very grateful to have the opportunity to be able to talk through this because I've been frustrated by some of the accounts that I've been

reading and not really having a good forum to be able to kind of lay out the whole story and address questions in a straightforward manner. So I really do appreciate it.

You know, I'm a doctor and long before I had this role I was a doctor at San Francisco General Hospital and I took care of lots of patients with tuberculosis. Many of them were medically indigent and poor people and we had to face——

Senator HARKIN. Excuse me. I was hoping to have Mr. Speaker so he could hear the proceedings. He really is a witness for our second panel and, like anyone; I wanted to make sure he could hear the proceedings before. I thought we had him before.

Well, we'll try to get him in between the panels. I'm sorry, Dr. Gerberding. We will not be interrupted again. Go ahead.

Dr. GERBERDING. Thank you. As I was just starting to mention, I've had a lot of experience as a doctor with patients with tuberculosis in an urban environment, and I know how important it is to balance the care and empathy that you have for the patient with your responsibility to protect people's health. I just want to say very overtly in this case that as a doctor I have enormous empathy for this patient and certainly his bride and his family and all of the stresses this whole situation has caused to them. He's got a very serious illness and I'm glad he's in the right place and I hope he gets the right treatment. Everything looks promising at this point in time, but we have to remember that above all we're dealing with an individual who has a very serious disease and I think that needs to be behind our thinking in all of these cases.

Let me talk a little bit about what should have happened here. Since 2002 there have been 72,000 cases of TB diagnosed in the United States. Each time a case of TB is diagnosed, it needs to be tested for drug-resistance, health officials need to be notified, and appropriate steps need to be taken to make sure the patient gets treatment and the public is protected from exposure during the period of contagion.

Seventy-two thousand cases represents the total of cases since I've been the CDC Director, and I can tell you in that period of time I have never had to issue a Federal order of isolation until this time. In fact, our records indicate we haven't issued a Federal order of quarantine since 1963, when a quarantine order was issued for smallpox, and I don't think any CDC Director has ever had to issue an order for tuberculosis. So this is a really unprecedented and unusual situation. The vast majority of times in the last 5 years of TB cases have been managed by local and State health officials without this kind of complication. The system has worked very well to protect the public's health, and on the handful of cases local isolation orders have had to occur, occasionally State isolation orders have been invoked. But we've always been able to make the system work on behalf of both the patient and the public. So we have to understand what changed in this particular situation.

Now, in this case what should have happened is that the diagnosis should have been made, the drug susceptibility testing should have been done, and health officials should have been alerted. Those things were done. There's been some confusion about why did it take so long to know that he had XDR TB and the reason

for that is this is a very slow-growing organism and it takes a long time to do the test when the organism is slow-growing. So there's nothing about the time line from diagnosis of the disease to diagnosis of drug resistance that is unusual, although there are some new opportunities that Dr. Fauci might talk about to speed up that process using new technology and new diagnostics that are in the pipeline.

The patient was prescribed traditional four-drug first line therapy, but once it was learned that he had multi-drug-resistant TB that treatment would have been ineffective, and so he was essentially untreated until he ended up at National Jewish and could be started on therapy.

The local public health officials assessed the risk. They determined that it was not zero. They recommended measures to protect others. Basically, in the vast majority of situations like this they operate under a covenant of trust. They give advice to the patient, they explain what needs to be done to provide protection. Patients generally cooperate. As I said, almost all of them cooperate with that experience. Certainly, in my own experience I've never been in a situation where we were as surprised to see a patient choose a different route. But of course, in this situation the patient had very compelling reasons to make an alternative judgment about what was in the best interests of himself and the people around him.

In Georgia, if a patient is to be isolated in an involuntary manner it takes a court order and the patient must first demonstrate that he is not compliant with medical advice. So the State could not issue such an order until the patient actually did something that was against medical advice. That's the way the laws in Georgia are written.

If the State felt that they couldn't isolate the patient, they could contact CDC to determine whether or not we could use our Federal quarantine authorities in this case. Our authorities allow us to act when the State fails to contain the patient. They allow us to act in a situation of interstate movement, when a patient's moving from one State to another. They're written to act, to allow us to prevent the importation of tuberculosis into our country. So those are conditions in which we can issue a Federal order of isolation.

We recognize that in this case everyone was giving the patient the benefit of the doubt and assuming that we would be able to find a way to satisfy our public health responsibilities as well as his personal needs.

On May 10, I don't know from a CDC perspective what was said in a meeting, but—because our quarantine officer was not present, but I do know that the health department met with the patient to explain his drug-resistant tuberculosis and what needed to be done, and following that meeting Georgia Department of Health did contact the quarantine officer at CDC and request information on what to do if the patient did not follow medical advice and made a decision to travel internationally. So we were contacted to ask what options did exist if a patient did not follow the advice of the health department and made alternative decisions, and that advice was provided by the quarantine officer. The e-mail from the Georgia

State Health Department did not contain specifics and indicated travel was intened in 3 weeks.

We know the next day the patient made a decision to contact the airlines and move up his flight date and then traveled on the 12th to Europe. His fiancée did not change her plans apparently and traveled on the 14th, as the patient had originally intended.

On May 18, CDC was notified by the health department that the patient might be in Greece. So we contacted airlines to try to ascertain if in fact he had flown out of the United States and went to Greece. We were able to contact Delta, which was the plane that he was scheduled to fly on the 14th, and we looked at the days 3 days before, 3 days after. The airline was very cooperative, could not find any information suggesting that the patient had left the country. So we had no documentation.

During this time we were also on the Internet trying to find the patient's addresses, telephone numbers, the father's telephone numbers, and so forth, trying to track down family members, including the father-in-law of the patient and his father, to see if we could contact them by cell phone or by other means to figure out their whereabouts. We were unsuccessful in contacting them during this period of time.

On May 22, our laboratory determined that the patient actually had extensively drug-resistant TB, a form of TB that's extremely difficult to identify and to treat. CDC contacted the Customs and Border Protection and asked them to put the patient on the lookout watch list because of this extensively drug resistant tuberculosis (XDR TB). They were very cooperative. We were able to learn when the patient was scheduled to return. They were able to put that alert out for all of their border officers and that day we were able to make contact with the patient's father-in-law by cell phone. He was able to tell us that yes, in fact the patient had been in Greece, they were traveling internationally, they were on their honeymoon, he didn't know where they were; he would try to contact them.

About 12:30 a.m. in Rome on May 23, the patient did in fact return CDC's messages and contact CDC in a very cooperative mode, as his family had asked him to do, and we were able to have conversations with him while he was in Italy. Granted, it was late at night for him; those conversations went on over the next 24 hours.

The communication from CDC focused in three areas. One is to inform the patient that he must not fly on commercial airlines because he had extensively drug-resistant TB. The second was that it was important that he report to a chest hospital in Italy so he could be evaluated. We were concerned that since he hadn't been treated in the last 2 months he could be getting sicker and potentially more infectious and that he needed to be seen by a medical physician so that we would have information about what other decisions and options were available.

We also provided the patient with information about what the options might be for bringing him home, either in the short term or in the long term. As the U.S. Government, the policy in the State Department is that travelers have to provide their own transportation home if they have a medical emergency, including a communicable disease. But we felt in this situation, since he was not only a risk to himself but a risk to other people that we really

should try to see if we could do something to facilitate and help him get home.

Options we considered included an air ambulance, which his insurer may or may not have paid for, and we made efforts to contact Kaiser Insurance beginning that day when we found out who his insurer was to try to ascertain if Kaiser could help us. We also contacted USAMRIID because the military has an isolator that they can roll on or off aircraft and put patients in respiratory isolation to bring them home without posing a risk to the pilots or the crew. That option was not immediately available and it would have taken some time to get TRANSCOM to order a military aircraft, and how we would pay and reimburse the DOD for that was something that we had not planned for and that's an area in our action plan that we need to go back and revisit.

We also considered CDC aircraft. CDC has two small airplanes that we have to have available 24/7 to support our Strategic National Stockpile and we have the CDC aircraft that this committee has helped us support in the context of SARS and the many public health emergencies where we've had to take a fast action and move samples or people or specimens very quickly.

Unfortunately, our aircraft is not configured to allow safe transport of patients with respiratory diseases that require isolation. There is no way to completely separate the air in the airplane from the pilots or the crew of the aircraft. We used the same plane when we flew the patient from New York to Atlanta, but in that case it was a short flight. It's not a short flight from Europe to Atlanta and so we were just not able to safely orchestrate this.

We tried to think of various things we could do to rig the system to make the plane air-safe, but we really could not transport the patient in respiratory isolation. We have a gap there in our ability to move patients forward.

But I want to be completely clear that we looked at every option and we have done a lot of analysis since that time to figure out how can we close this gap in our ability to transport a patient who requires respiratory isolation. Keep in mind that at that time we did not know how infectious the patient really was because he'd not been successfully treated at any point in time.

The patient understandably was probably frightened. Here he was on his honeymoon. He's told now he's got extensively drug-resistant tuberculosis. He's told he has to go to a hospital he knows nothing about. We asked him to call the Embassy, to the travel assistance program, because the State Department has a loan program to help travelers whose insurance or private means don't allow them to get home.

So there are many options that we presented, but I think in retrospect, the bottom line was the patient was fearful he was going to be isolated out of his own country and made a personal decision to travel, as he put it, underground to avoid any detention that could really provide a severe restriction of his movement over the long run.

So even though there was a border lookout for the patient, he was able to get into the United States through a very specific error that Homeland Security has addressed, accounted for, and is in the process of correcting when he returned across the border into the

United States from Canada. But after he crossed the border, CDC made contact with him. He was cooperative. He went to Bellevue Hospital in New York City, as we asked him to do. The patient was immediately met by CDC's quarantine medical officer in New York City.

We issued the Federal isolation order there. He was hospitalized for evaluation. His sputums were checked. He was smear-negative (subsequently, culture positive once again), as he is still smear-negative in Denver Jewish. What that really means is that, while his cultures are positive, he can transmit TB, he's not highly infectious, meaning he does not have so many bacteria that you can directly see them under the microscope but he is infectious nonetheless. I think his care and management from that point forward is clear to everyone.

So basically here we are in a situation where we have tried to balance the need to respect the patient's needs and wants and emotional state and compelling needs with our requirement to try to protect the people's health. We gave the patient the benefit of the doubt at several points here and in those cases we failed to take the aggressive action that we could have used with legally sanctioned methods to restrict his movement more effectively.

Let me just define those three places so we can be explicitly clear. First of all, up front before the patient left the United States, we believe that we could strengthen our States' ability to restrict the movement of patients before they demonstrate noncompliance with a medical order. If we believe the patient has a strong intent to put others at risk, we need to have confidence we can take action absent documentation of intent to cause harm.

We also think we need clarification in the quarantine statute. It does not explicitly address exportation, meaning movement of patients out of the country. It expressly addresses importation and movement of patients from one State to another. So we may be able to use the existing statute with a clarification of intent, but we do need to identify what our responsibilities and authorities are under the statute and make a decision about whether a change is needed.

I want to emphasize this because the whole history of quarantine has been devoted to keeping people out and containing them, and it is the first time that we've really had to address keeping people in our country. So our statutes weren't really designed with this modern age of global travel and the vast multiple dimensions of international travel that we experience.

The second point I want to make is about the speed of notification. There were several ways in which CDC made required notifications in this event. I mentioned we notified the Customs and Border Protection to help us try to prevent the patient from entering the country. We also cooperated with TSA to put in a no-fly order. I have to say, every time Homeland Security was very helpful to us and stepped up to the plate to try to facilitate what we were trying to do, even though this was the first time they'd been in this situation of trying to use their tools and authorities for an infectious disease threat.

We know that we can fine-tune our notification, but when you look at the whole time line of this event, even if we had notified in all of these cases sooner, it would not have prevented the pa-

tient's movement, nor would it have prevented the passenger exposures on the flights. So we need to notify faster, but it would not have prevented the problems that were seen.

We did notify the World Health Organization about a half a day later than we should have. When we contacted the World Health Organization to tell them that we had a patient that we couldn't locate, who may be exposing people in Europe, they notified us that they did not consider this to be a public health emergency of global significance, they were not going to take action, but when we had more specifics and more specific information that there were passengers at risk to get back to them and they would respond.

So when we got the travel information of the patient's itinerary, we returned that information to the World Health Organization and at that point they contacted ministers of health and CDC initiated the process of contact investigation for the travelers along with international partners.

The last point of improvement I believe is our ability to move patients with respiratorily transmitted diseases in aircraft. We would love it if everyone had private insurance that paid for med-evac, but most people don't, and that's an alert to passengers that they need to look at their own insurance options when they travel. We would love it if we had a large pot of money so any person in the United States who had a problem abroad could be paid to have transport home by their government. I don't think that's going to be realistic.

But when we're in a situation where someone is putting someone else at risk by flying commercially, we need to be able to move that person safely home in an appropriate aircraft. We have a plan to reconfigure the craft that we have at CDC. We're hoping that we'll be able to have the authority to go ahead and make that configuration change so that we don't have to ever have this conversation again. It's my belief that if the patient could have been reassured of affordable and safe transport home that he would have been unlikely to fly home commercially and we could have eliminated a great deal of the difficulty for at least those passengers flying from Czechoslovakia to Canada.

So our after-action review process has already begun. Last Tuesday we gathered all accountable CDC parties together, went through this in great detail, began to patch together the time line, which I'm sure will evolve and improve as we get information from other people, and have begun to initiate actions to change.

One of those actions involves DHS and we've already agreed that we can accelerate all of this communication about notification by simply having the CDC operation center go through the Secretary's operation center right to the national operation center. So DEOC to SOC to NOC will get us into a mode where Homeland Security can make the entire cascade of notification work effectively.

We also have initiated an internal review at CDC to assure that all of the conduct of CDC employees, including the father-in-law, is consistent with ethical standards. We're making sure our bio-hazard and safety procedures are appropriate and that there is no situation involving CDC or CDC employees that was a problem here.

Last, we have made the decision, to assure the objectivity of this process, to work with the inspector general's office to have a look at the conduct of the CDC employee, who I'm sure was torn between his responsibilities as a CDC scientist and his role as father of the bride in this particular situation. I want to emphasize his cooperation with us.

Then last, we'd like to bring forward to the committee our plan for configuring our aircraft to allow us to move patients in respiratory isolation.

PREPARED STATEMENT

So let me close by thanking you for your patience. You know I'm also in the very embarrassing situation of having to be at another hearing simultaneously to this one, so you let me go first. I would really like to make myself available to you after the Q and A in the future if there are any other questions that the committee would have for me that I can't stay for in the second panel.

So thank you very much and I hope this has been helpful.
[The statement follows:]

PREPARED STATEMENT OF DR. JULIE L. GERBERDING

Good morning, I am Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention within the Department of Health and Human Services (HHS). Chairman Harkin, ranking member specter, and other distinguished members of the Subcommittee, it is my pleasure to be here to discuss with you CDC's ongoing investigation of a U.S. traveler recently diagnosed with extensively drug resistant tuberculosis. Before I move to the specifics of this investigation, I want to highlight the priority CDC places on global health protection and disease prevention at home and abroad. CDC's four guiding Health Protection Goals—Healthy People in Every Stage of Life, Healthy People in Healthy Places, People Prepared for Emerging Health Threats, and Healthy People in a Healthy World—serve to focus our programmatic efforts and financial investments to achieve the greatest health impact, and this case has reinforced the critical importance of each of these goals.

CDC's goal of Healthy People in a Healthy World prioritizes our global health activities to assure that people around the world will live safer, healthier and longer lives through health promotion, health protection, and health diplomacy. The current XDR TB situation has involved many public health officials from around the world who acted together to protect people's health in a circumstance where an individual with drug resistant tuberculosis may have served as a source of exposure. I want to thank the public health officials from around the world that came together in a network of public health protection to work through the complexities involved in this case and take steps necessary to protect the public's health. It serves as a reminder as we move into the era of emerging infectious diseases that we need to assure that this global health protection network works every time for everyone, anywhere. And CDC will continue to provide leadership and assistance to our global health partners to strengthen that network further as we go forward. This statement highlights some of the key local, State, Federal and international partnerships that contribute to this global health protection network. I will begin by providing some background information on tuberculosis before describing CDC's role in responding the current XDR TB case.

DEFINITION

Tuberculosis is an airborne infectious disease that is spread from person to person, usually through coughing, sneezing, speaking, or singing. In the late 19th and early 20th centuries, until the introduction of streptomycin in the 1940's, TB was one of the leading causes of death in the United States. Currently, the World Health Organization (WHO) reports that one in three people in the world are infected with dormant or latent TB. TB is a slow growing bacterium that often takes weeks to culture. Only when the bacteria become active do people become ill with TB. Bacteria become active as a result of anything that reduces the person's immunity, such as HIV, advancing age, or some medical conditions. TB bacteria can also become active in individuals that are not immunocompromised. Currently, TB that is not re-

sistant to drugs can be treated with a six to nine month course of “first-line drugs” (the most effective), including isoniazid and rifampin; this treatment cures over 95 percent of patients. However, since people in many resource-poor countries lack access to appropriate treatment, nearly 9 million people in the world develop TB disease each year and about 1.6 million die.

TB that is resistant to at least isoniazid and rifampin is called multidrug-resistant (MDR) TB. MDR TB requires treatment for 18–24 months with “second-line drugs” that are much less effective, often poorly tolerated by the patient, and far more costly. The cure rate is 70–80 percent under optimal conditions, but is usually closer to 50 percent. Many countries with a high TB burden find it impossible to treat MDR TB patients because of the cost of second-line drugs, and the more sophisticated laboratory services to diagnose resistance to drugs, and more intensive programmatic support required to administer the drugs. Extensively drug-resistant TB (XDR TB) is a subset of MDR TB caused by strains of bacteria that are resistant to the most effective first- and second-line drugs. Reported mortality rates among persons with XDR TB are extremely high. Among non-immunocompromised persons, reports indicate that less than 30 percent of patients can be cured, and more than half of those with XDR TB die within 5 years of diagnosis. Among immunocompromised persons, illness is more severe, and mortality rates are even higher and death occurs within a shorter time.

The risk of transmitting any type of TB can depend on several factors, including the extent of disease in the patient with TB, the duration of exposure, and ventilation. Both regular TB and drug-resistant TB bacilli become aerosolized when a person with TB disease of the lungs or throat coughs, sneezes, speaks, or sings. These bacilli can float in the air for several hours, depending on the environment. Persons who breathe air containing these TB bacilli are at risk for becoming infected.

SCOPE OF THE PROBLEM

In response to anecdotal reports from physicians who were finding cases of TB that were unresponsive to the first-line and second-line TB drugs, in 2005 HHS/CDC and WHO jointly conducted a survey, with support from the U.S. Agency for International Development, which examined about 18,000 patient specimens tested during 2000 to 2004 by Supranational Reference Laboratories. Researchers examined the drug-resistant isolates, and found that 10 percent of the MDR TB isolates actually met the definition for XDR TB. XDR TB was identified in 17 countries from all regions of the world, most frequently in the former Soviet Union and other Asian countries. However because many countries do not routinely test all isolates for resistance to second line drugs, the precise global incidence of XDR TB remains uncertain. Because of the ease with which drug resistance can occur (due to the use of second-line drugs in suboptimal conditions, changes in program focus away from TB case management, interruptions in drug availability because of supply management/resource availability/patient drug noncompliance, high HIV prevalence), XDR TB could be much more widespread than this survey shows. The ability of the disease to develop resistance to treatments and to travel easily across borders makes worldwide TB control efforts critical.

TB AND THE THREAT TO THE UNITED STATES

Between 1993 and 2006 in the United States, there were 49 cases of XDR TB reported to HHS/CDC. By comparison, 13,767 TB cases (a rate of 4.6 cases per 100,000 persons) were reported in the United States in 2006 (the most recent year of aggregate annual reporting). The 2006 TB rate was the lowest recorded since national reporting began in 1953. While the total number of MDR and XDR TB cases is relatively small, their impact on U.S. TB control programs can be significant in terms of human capital and financial resources. One patient with MDR or XDR TB requires a minimum of 18–24 months of treatment. Recently collected data show that in-patient costs alone can average \$500,000 per case.

XDR TB continues to be widely distributed geographically abroad and is cause for public health concern in the United States, though the overall domestic risk of XDR TB currently appears to be relatively low. However, due to the ease with which TB can spread, and given its significant health consequences, XDR TB will continue to pose a serious risk to the United States, as long as it exists anywhere.

TB PREVENTION AND CONTROL: PUBLIC HEALTH PARTNERSHIPS IN ACTION

Generally, TB is a condition that is detected and treated by medical care practitioners. As with other infectious diseases, State, local, and territorial health departments serve important functions to support and augment the medical care system. These “front line” public health agencies are in direct contact with medical care pro-

viders and patients, providing important TB control services such as laboratory support, surveillance, contact tracing, and patient counseling. These agencies also generally possess legal authority to isolate or quarantine patients in those rare instances where traditional doctor-patient relationships or other means have failed to protect the community.

At the Federal level, HHS/CDC serves several critical roles in controlling TB. First, HHS/CDC provides leadership and scientific support for TB control efforts, both nationally and internationally, including our global efforts to eliminate TB and stem the emergence of XDR TB as a health threat. Secondly, HHS/CDC provides approximately \$100 million annually in support to State, local, and territorial health departments for TB control efforts. Third, State and local public health departments routinely test samples of respiratory secretions from patients in order to diagnose tuberculosis and for some State laboratories, including Georgia, HHS/CDC routinely conducts second line drug susceptibility testing. HHS/CDC receives isolates from approximately 20 State laboratories each year as part of those laboratories' regular referral process. Each year HHS/CDC conducts drug susceptibility tests for approximately 1,000 samples. Fourth, HHS/CDC has the capacity to assist State or local authorities with its scientific resources. HHS/CDC may also use its Federal legal authorities to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States or between U.S. States. As I will describe, HHS/CDC's involvement in the recent case spanned all of these roles.

THE CURRENT XDR TB INVESTIGATION: LOCATE, ISOLATE, TRANSPORT, INVESTIGATE

The following narrative is based on information assembled and reviewed in time for this testimony. The ongoing HHS/CDC investigation involves a U.S. citizen with potentially infectious XDR TB who traveled to and from Europe on commercial flights. In late March, the patient was diagnosed with TB by his doctor. Once diagnosed, Fulton County Health Officials became involved in managing the potential public health risk to others.

On May 10, the Fulton County Health Department became aware that the patient's TB strain was resistant to the first-line of antibiotic treatments. This same day, the county health department met with the patient and his family to inform them of the diagnosis of MDR TB. Our understanding, from conversations with the county health officials, is that they orally advised the patient to forego his planned travel abroad. On the evening of May 10, the Georgia Health Department emailed HHS/CDC's Atlanta Quarantine Station and reported that they were aware of an MDR TB patient (patient was not identified) that may intend to travel in three weeks. HHS/CDC exchanged emails with the Georgia Health Department with options to prevent travel including written notification under local authority. In the days following this meeting, Fulton County Health Officials attempted to serve the patient with written notice advising that the patient not travel, but the patient could not be located at either his residence or business.

It should be noted that normally when a patient has tuberculosis, he or she voluntarily complies with recommended treatment and recommendations to ensure that they don't put themselves in situations where they could potentially expose others to a serious health threat. Public health practitioners have a high success record using voluntary means of information and advice. In fact, the vast majority of TB patients comply with treatment recommendations, including remaining in isolation units in hospitals or in isolation at home until infectiousness has resolved without the need to invoke State or local legal authorities. It is extremely rare that Federal quarantine or isolation authority is required to manage domestic TB cases.

On May 18 after the patient left the United States, HHS/CDC's Division of Global Migration and Quarantine was notified that the patient traveled internationally against medical advice and his whereabouts were unknown. At this point, HHS/CDC's public health mission focused on locating the patient, isolating him, ensuring safe transportation and contact tracing. Between May 18 through the 22, HHS/CDC worked with Fulton County health department, Georgia State Department of Health, commercial airlines and the patient's family to locate him. In addition, on May 22, HHS/CDC laboratories determined that the patient had the rarer and deadlier subtype of XDR TB.

On May 22, HHS/CDC quarantine officials requested that the Customs and Border Protection (CBP) Atlanta office arrange to have the patient detained upon reentry to the United States. On both May 22 and 23, HHS/CDC spoke with the patient in Rome, Italy and informed him of his XDR TB diagnosis; explained the severity of the disease; instructed him to terminate all travel and to cease use of commercial air carriers; and initiated conversations about the need for isolation, treatment,

and travel alternatives. Despite assurances from the patient that he would not travel, it was discovered, on May 24, that the patient had checked out of his hotel.

With the patient's exact location and intention to travel unknown, HHS/CDC contacted the Transportation Security Administration (TSA) on May 24 and requested them to exercise their authority to prevent the patient from boarding a commercial aircraft and thereby mitigating the risk of transmitting the disease on another long-distance commercial flight destined for the United States. On May 25, HHS/CDC learned from CBP that the patient had traveled via commercial airliner from the Czech Republic to Canada and subsequently reentered the United States the previous evening. HHS/CDC then notified the Public Health Agency of Canada and requested they initiate efforts to get the passenger manifest of the patient's inbound flight to North America. HHS/CDC called WHO in Geneva on May 24 and the HHS Secretary's Operations Center, the designated Focal Point for the United States under the revised International Health Regulations (2005), officially notified the WHO Secretariat of the case on May 25, even though the Regulations do not come into force for the United States until July 17, 2007.

On May 25, after repeated prior attempts, HHS/CDC officials made contact with the patient on his cell phone and directed him to report immediately to the Bellevue Hospital in New York City where he would be served a quarantine order for isolation and be evaluated. He followed this direction, and at Bellevue was served a Federal order of provisional isolation and medical examination authorizing medical evaluation and respiratory isolation for 72 hours for extensively-drug resistant tuberculosis (XDR TB). The patient was later safely transported to Grady Hospital in Atlanta, Georgia via HHS/CDC aircraft and was issued a Federal order that mandated continued isolation on arrival in Atlanta, GA. As part of this process, the patient was advised that he could request an administrative hearing to review the order but he did not request such a hearing. On May 31, he was safely transported by private airplane to National Jewish Medical Center in Denver, Colorado accompanied by his wife and a CDC quarantine officer. On June 2, HHS/CDC rescinded the Federal quarantine order for isolation because Denver health officials assumed public health responsibility for this patient. The patient is currently under the quarantine authority of Denver County.

HHS/CDC is currently investigating the source of the patient's XDR TB. HHS/CDC is conducting an epidemiological investigation to look back at the patient's activities prior to his diagnosis in hopes of learning the source of the exposure. The patient has a history of travel to numerous locations outside of the United States. Sequences of DNA from the patient's TB strain do not match any currently on file in HHS/CDC's TB fingerprinting library. HHS/CDC is making efforts to compare it with TB fingerprinting libraries in other countries.

HHS/CDC RECOMMENDATIONS FOR PASSENGERS

Though the risk of transmission to the other passengers on the flights the patient took is low, it is not zero. In accordance with the WHO TB and Airline Travel Guidelines, and to ensure appropriate follow-up and care for persons who may have been exposed to XDR TB, HHS/CDC has recommended that passengers aboard the two transatlantic flights longer than 8 hours in duration who were seated in the same row as the patient, those seated in the two rows ahead and the two rows behind, and cabin crew members working in the same cabin should be evaluated for TB infection. This includes initial evaluation and testing with re-evaluation 8–10 weeks later. Because undiagnosed, latent TB exists in the general population, it is reasonable to expect that some of the passengers will test positive because of a previous exposure to TB, and not because of exposure on the flight in question. While we believe that passengers seated outside the immediate vicinity of the patient are at extremely low risk of contracting XDR TB, given the serious consequences and limited treatment options of XDR TB, we are notifying all U.S. residents and citizens on these flights and encouraging these individuals to seek TB testing and evaluation.

HHS/CDC is taking the lead in contact tracing of the U.S. citizens on these flights and is coordinating with other countries for the contact tracing of their citizens. As of June 5, HHS/CDC has had direct contact with 245 of the approximately 276 U.S. citizens and residents on Air France 385. Of the 26 high priority passengers, seated in the same row, two rows in front or two rows behind the patient, HHS/CDC has spoken directly with 24 of these individuals.

ISOLATION AND QUARANTINE, AN HHS–DHS PARTNERSHIP

To contain the spread of a contagious illness, public health authorities rely on many strategies. Two of these strategies are isolation and quarantine. Both aim to

control exposure to infected or potentially infected persons, and both may be undertaken voluntarily or compelled by public health authorities. The two strategies differ in that isolation generally applies to persons who are known or suspected to have a communicable disease, and quarantine generally applies to those who have been exposed to a communicable disease but who may or may not become ill. Isolation is a standard procedure used in hospitals today for patients with tuberculosis (TB), and in most cases isolation is voluntary; however, many levels of government (Federal, State, and local) have basic authority to compel isolation of infected people to protect the public. State and local governments have primary responsibility for isolation and quarantine within their borders and conduct these activities in accordance with their respective laws and policies.

The Department of Health and Human Services has authority under section 361 of the Public Health Service Act to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States and between States. HHS/CDC, through its Division of Global Migration and Quarantine, is authorized to detain, medically examine, or conditionally release persons suspected of carrying certain specified communicable diseases. The communicable diseases for which Federal isolation and quarantine are authorized are established by Presidential order and currently include infectious TB, cholera, diphtheria, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza with pandemic potential.

HHS/CDC relies primarily upon DHS for the enforcement of isolation and quarantine orders at the borders, but may also rely on other Federal law enforcement agencies and State and local law enforcement. By statute, our DHS partners at the borders—Customs and Border Protection (CBP) and Coast Guard officers—aid in the enforcement of rules and regulations relating to quarantine and isolation. Violation of Federal regulations regarding quarantine and isolation constitute a criminal misdemeanor, punishable by fine and/or imprisonment. Federal public health authority includes the authority to release persons from quarantine or isolation on the condition that they comply with medical monitoring and surveillance.

HHS/CDC maintains a close partnership with DHS and its agencies. DHS and HHS signed a memorandum of understanding (MOU) in 2005 that establishes specific cooperation mechanisms as part of a broad framework for cooperation to enhance the Nation's preparedness against the introduction, transmission, and spread of quarantinable and serious communicable diseases from foreign countries into the States, territories, and possessions of the United States. DHS has charged the Homeland Security Institute with facilitating the implementation of the MOU and HHS/CDC's Division of Global Migration and Quarantine is collaborating in this effort. Concurrently, HHS/CDC has conducted table top exercises at ports of entry in cooperation with DHS' component agencies and State and local partners to develop and refine communicable disease response plans.

The partnership between CBP and HHS/CDC is particularly vital, as CBP officers act as HHS/CDC's "eyes and ears" on the ground. In addition to assisting with the enforcement of Federal quarantine and isolation, HHS/CDC helps to train CBP officers to identify and respond to travelers, animals, and cargo that may pose an infectious disease threat. CBP also assists quarantine officials with the distribution of health risk communication materials for the traveling public, such as notices that alert travelers of possible exposure to communicable disease threats abroad and offer guidance on steps they can take to protect themselves.

NEXT STEPS, WHAT MORE CAN BE DONE

With the support of Congress and the President, and in accordance with the recommendations of the Institute of Medicine (IOM), HHS/CDC is investing in building a Quarantine and Migration Health System that meets the needs of the 21st Century. HHS/CDC is enhancing the numbers and competencies of staff, training, physical space, and utilization of technology to meet the Quarantine System's evolving, expanding role. This has included the creation of additional quarantine stations at airports and other major ports of entry into the United States. HHS/CDC has expanded this critical public health infrastructure to 20 stations and is focusing on fully staffing these stations.

By continuing to expand the capacity of the U.S. Quarantine and Migration Health System through science, partnership, and preparedness, HHS/CDC will be better equipped to play an active role in worldwide biosurveillance, to coordinate nationwide response to global microbial threats of public health significance and to protect the U.S. public from communicable disease threats. The President has requested an additional \$10 million in fiscal year 2008 to support the further enhancement and expansion of the Quarantine and Migration Health System.

In addition, HHS/CDC has been working to update interstate and foreign quarantine regulations [42 CFR Parts 70 & 71] to codify procedures that more completely reflect the 21st century implementation of disease containment measures such as isolation and quarantine, and that strengthen the nation's public health security at ports of entry. On November 30, 2005, HHS/CDC published a notice of proposed rulemaking (NPRM) to update the interstate and foreign quarantine regulations [42 CFR Parts 70 & 71]. Once adopted, these changes will represent the first significant changes to these regulations in 25 years.

Key provisions proposed include: more explicit due process protections for written orders and an administrative review hearing; expanded reporting of ill passengers on board air carriers; and requirements that will facilitate the timely transmittal of passenger and crew contact information to HHS/CDC to ensure quick notification of exposure to communicable disease threats. These procedures are expected to expedite and improve HHS/CDC operations by allowing immediate medical follow-up of potentially infected passengers and their contacts. HHS/CDC received over 500 pages of comments from approximately 50 organizations and individuals regarding the proposed rule. HHS/CDC is currently addressing issues raised during the public comment periods, including working with DHS to most efficiently share contact information, and developing a draft final rule.

To control TB, HHS/CDC and its partners must continue to apply fundamental principles including: (1) State and local TB programs must be adequately prepared to identify and treat TB patients so that further drug resistant cases can be prevented; (2) TB training and consultation must be widely available so that private health care providers recognize and promptly report tuberculosis to the public health system; (3) State and local public health laboratories must be able to efficiently perform and interpret drug susceptibility and genotyping results in TB specimens; and (4) CDC and local health authorities must work collaboratively to ensure that isolation and quarantine authorities are properly and timely exercised in appropriate cases.

The prospects for development of new TB drugs also are promising and those efforts must continue. There are at least 4 new anti-TB compounds entering human trials while others are in advanced preclinical testing. These new compounds represent new drug classes that may offer promise for treating resistant cases.

CONCLUSION

We have begun a careful review of our protocols and capabilities. First and foremost, we are reminded that infectious diseases are not a thing of the past, and that we need to continually adapt our prevention and response capabilities in an era of increasing threat and globalization. We are reminded that almost all infectious disease cases are effectively handled within our existing systems of care by patients, clinicians and local public health authorities, and that it is important to continue to reinforce and augment these existing roles and relationships. Our public health protection network assisted us in responding to this event in a more timely and coordinated manner. Public health officials continue a long tradition of working together on every level to identify, contain and mitigate the spread of communicable diseases in U.S. communities and abroad.

The case also reminds us that there are a number of existing channels that we can leverage more effectively in the future. Through the Global Health Security Action Group—a group of senior policy officials, top scientists, and media experts from the ministries of health of G-7 nations, Mexico, the World Health Organization and the European Commission—we can quickly convene relevant public health officials via phone and video conferences to convey information on cases like this to our key allies in a more timely and effective way.

In an age of global air travel, infectious diseases can, and do, cross geographic borders every day. People can be infected with a disease and have few visible indications, people can vary in terms of how infectious they are, it is often not possible to rapidly test and confirm whether a person has an infectious disease, and people's health status can change quickly and unpredictably. We will never be in a position where we can guarantee that infectious people will not cross borders, but we will work to ensure that the measures available are as effective as possible. And so too this case reinforces the need to advance our efforts to modernize our Quarantine and Migration Health System and update Federal quarantine regulations; improve our information technology and communications capabilities; and define and exercise our capabilities and relationships with international, Federal, State, and local partners so that we are prepared to deal with situations that pose a threat to public health. We believe the lessons learned from this case will improve HHS/CDC's ability to protect the Nation's health in our ever-changing global environment.

Senator HARKIN. Thank you, Dr. Gerberding. Are you telling me that you can't stay?

Dr. GERBERDING. No, I'm staying for what we're doing right now. But on the second panel, there's a House hearing going on at the same time and they are expecting me there probably already.

Senator HARKIN. Well then, thank you very much, Dr. Gerberding. I allowed you to go beyond time because I wanted to get you on and make it clear on the record the position of CDC. But there are a lot of questions I'm sure that I and others have regarding CDC and the time line and why things weren't done at a certain time.

But I think it's important to go to Ms. Spero now, basically, Ms. Spero, to answer the question of why this person got through the border. Ms. Spero is Deputy Commissioner of the United States Customs and Border Protection of the Department of Homeland Security. We wanted you here basically to let us know how this guy got across the border, Ms. Spero. Please proceed.

**STATEMENT OF DEBORAH J. SPERO, DEPUTY COMMISSIONER,
UNITED STATES CUSTOMS AND BORDER PROTECTION, DEPARTMENT OF HOMELAND SECURITY**

Ms. SPERO. Thank you, Chairman Harkin, and good morning to you and the distinguished members of this committee. I am here before you today to discuss the role of U.S. Customs and Border Protection, CBP, in the Federal Government's efforts in late May to track down a U.S. citizen, Mr. Andrew Speaker, who was traveling with his wife internationally while he was infected with a rare strain of tuberculosis. I hope to provide you with such additional details as can be discussed in this forum of what happened when a CBP officer encountered the traveler and his wife crossing the land border with Canada at the Port of Champlain, New York, and allowed them to enter the United States contrary to CBP instructions. We will also update you on our resulting follow-up actions.

Let me state at the outset, CBP had an opportunity to detain Mr. Speaker at the border and missed. That missed opportunity was inexcusable and it appears at this stage to be largely the result of a CBP officer failing to follow procedures and instructions. That failure is felt collectively by all of CBP's leadership and the front-line employees whose good work and reputations are tarnished by such actions. There is no criticism that can be leveled today or in the coming weeks by outsiders any harsher than the blame and frustration we have already turned on ourselves since the discovery of Mr. Speaker's entry into the United States on May 24.

The failure to detain this traveler unfortunately overshadows and negates a lot of the good work done in this particular case by CBP employees both before and after the encounter at Champlain. Specifically, the work of our other employees began in Atlanta on May 22, when CDC contacted our local field office about Mr. Speaker. As a result of this contact, on that day a nationwide alert was placed in our electronic systems that gave us the necessary information to intercept the traveler despite not knowing how or where he would attempt to enter.

We continued our efforts looking for Mr. Speaker's travel to the United States in the event he chose an alternate time, date, and

method of travel. When it was determined by our national targeting center that the traveler had entered, we alerted the CDC within hours of the entry.

Our efforts continued last week with CBP employees using our tools and information to identify Mr. Speaker's travel pattern and helped track down other passengers from his flights who are potentially at risk for tuberculosis from exposure to him.

Also overshadowed is all the good work of CBP officers on a daily basis. Just to put this incident in context, on that date, May 24, at the Port of Champlain, New York, we processed the entry of 1,296 vehicles, 1,378 commercial trucks, and we responded to numerous alerts that were properly referred for secondary inspection. Nationwide, on an average day CBP processes 1.1 million passengers and pedestrians, almost 71,000 trucks, rail and sea containers, over 240,000 incoming international air passengers, 327,000 incoming privately owned vehicles, and over 85,000 shipments of goods in just 1 day.

What should have been a textbook success story to demonstrate the effectiveness of our officers in carrying out their responsibilities and the value of our technology systems was overshadowed by the failure to stop this one traveler. There is no excuse or acceptable explanation to offer for failing to stop this individual at the border. I do not believe that it can be explained by any lack of tools or training, and I can assure you that the actions of the individual officer and the supervisors in Champlain are being fully investigated and appropriate action will be taken.

Because there is a required administrative process, I may not be able to say as much as I would like to today about these personnel actions. However, in a closed briefing we would be happy to provide the members with more detail on what took place in those critical few minutes in Champlain, New York.

In addition to the ongoing process with respect to the particular incident, we have taken some immediate steps in CBP to implement enhancements to our information technology systems and our protocols at the ports of entry to further reduce the possibility that a single officer on primary inspection could ignore clear instructions about a public health alert in the same manner ever again.

I would like to take a moment if I may in defense of the human element on the front line of America's borders and in all law enforcement that has been critically questioned during the past few weeks. While the human element, as we've seen, can be a weakness, it is also the source of our greatest strength. A great many of the threats we intercept on a daily basis at our ports of entry are caught not because of known alerts or watch lists already in a computer, but because of the training, the experience, and the judgment of our front-line officers in dealing with the unknown. It is the unknown threat that is still our greatest vulnerability.

We were in fact presented with such a threat in the Millennium Bomber incident, who was intercepted at the border with a car trunk containing explosives on his way to blow up a terminal at LAX in 1999. This is an example of an alert Customs inspector who acted, not because the traveler was a known threat or on a watch list, but because the inspector could rely on her judgment, her

training, and her experience to determine that something wasn't right with that traveler.

It was another front-line officer, this time a former Immigration inspector in Orlando, Florida, who in August 2001 denied entry to a Saudi national named Mohamed al-Qitani. Whether or not al-Qitani was, as thought by many, to be the 20th hijacker in the 9/11 tragedy, he was at a minimum an al Qaeda-trained terrorist. Again, this outstanding employee, now a CBP officer, used his training, his experience, and his judgment to deny entry to someone who in all probability would have tried to do harm to our citizens.

So it is important that, despite this most recent failure, we not lose sight of the value of that human element in inspection work and the dedication and daily contributions of CBP's front-line work force to the security of our country. Those who signed up to protect the homeland understand that we are expected to take the right action every single time. When we hit the mark, there will be precious little news because that is just doing our job. When we slip even once, it makes headlines. We accept that high standard of success without complaint because the mission is so important.

PREPARED STATEMENT

I will not offer any hollow promises today that human failings will never again occur among the 44,000 employees charged with the critical and complex mission of securing our Nation's borders. Similarly, I cannot guarantee that CBP will hit 100 percent success 100 percent of the time. But this incident has reinvigorated our focus on the mission of protecting the American people. It's caused us to reexamine how we perform that mission and reinforce in a way words cannot the critical importance of every single employee doing his or her duty.

Thank you and I would be happy to answer any questions.
[The statement follows:]

PREPARED STATEMENT OF DEBORAH J. SPERO

INTRODUCTION

Thank you Mr. Chairman for the opportunity to share with the committee some of the policy, procedures and processes we have in place with our Federal partners for the Nation's biodefense across our borders.

DHS is aware that the committee is acutely interested in the details and implications of the recent interactions with a patient infected with extensively drug resistant tuberculosis (XDR TB). We appreciate the opportunity to address this case with you and the actions we have taken to improve our biodefense posture. While this case is indeed interesting, it is extremely important to note that it poses no ongoing threat to public health in the United States.

The system created to effect an isolation order involves the Department of Health and Human Services (HHS), (including its Centers for Disease Control and Prevention (CDC)) acting under the authority of the Public Health Service Act and the Department of Homeland Security (DHS). The system functioned properly in this case. However, there appears to have been a single point of failure in this case—human error by an individual who may have failed to follow appropriate procedures. DHS continues to investigate this issue. While the investigation is pending, DHS has ensured that the individual is not carrying out inspection duties at the border.

The fact that a failure occurred underscores the need to implement additional failsafe mechanisms. U.S. Customs and Border Protection (CBP) has already made changes to its procedures designed to prevent this particular failure from occurring again. This was indeed a lesson learned and not simply a lesson observed.

The committee has also expressed its concern, which the Department shares, about the implications of this incident for biodefense at our Nation's borders. We share the genuine concern over the fact that our borders are not impervious to infectious diseases, in spite of the best efforts of the CDC and DHS and its components. Unless draconian health screening techniques are routinely implemented at each port of entry as a standard operating procedure for the millions of people crossing the border, there will always be opportunities for people who are ill to cross our borders undetected. The land border environment presents additional challenges because individuals claiming United States and Canadian citizenship are not always required to present passports that validate identity and citizenship. The Department is committed to addressing this security gap through implementation of the Western Hemisphere Travel Initiative (WHTI). Ultimately, the WHTI will provide technical enablers and controls to mitigate volume issues and ensure that high risk travelers are better identified at our ports of entry. WHTI implementation will enhance the screening process by increasing the number of travelers that can be efficiently queried at the time of entry through the ports of entry based on better documentation, identity and citizenship.

Currently, however, CBP officers are only able to query approximately 50 percent of land border crossers by requesting documents with machine readable zones (as noted previously, because individuals claiming U.S. and Canadian citizenship are not yet required to present documents denoting identity and citizenship) or by flat-fingering the query. In addition, the great majority of our 327 ports of entry are manned by law enforcement officials from CBP who have received no advanced medical training. CBP officers do have procedures to follow when a U.S. citizen or non-U.S. citizen appears to be ill and in need of medical attention at the border, and each is trained in those procedures. These procedures involve consulting medical personnel. Federal medical resources at the borders come from the CDC's Division of Global Migration and Quarantine (DGMQ), which provides that service at approximately 20 ports of entry. Even though steps were taken to fortify ports of entry with medical staff, even fully staffed quarantine stations are not in a position to perform routine health screening on all passengers crossing the border as a standard operating procedure. It is important to stress that individuals will not necessarily exhibit symptoms of illness and that CBP officer must make their best assessment within a limited period of time.

THE INCIDENT IN QUESTION

On May 22, 2007, CBP Port of Atlanta received information from the CDC regarding an individual, who traveled to Europe on May 12, 2007, noting that he is a carrier of a drug resistant form of tuberculosis.

A shift muster, a daily briefing for shift employees on significant policy and operational matters, was distributed and briefed to CBP Officers at all locations.

On May 24, 2007, at 18:18 hours, the individual arrived at the land border crossing at the Champlain, NY port of entry in a rental vehicle, accompanied by his wife.

More detailed information can be provided in a classified briefing. However, as a result of this incident, CBP initiated a systems enhancement (effective June 5, 2007) that will help ensure that officers will follow appropriate procedures when processing persons of interest seeking to enter the United States. This systems change will allow CBP to better account for and control all referred persons of interest for secondary inspection. It will also require that such persons undergo additional questioning and examination to determine whether they may be cleared or whether other appropriate action is warranted. The Department's long-term solution remains a WHTI enabled screening procedure that tackles the inherent problem of increasingly high traffic volume with improved query capabilities.

INFORMATION SHARING—UNITED STATES AND CANADA

In December 2001, former Secretary of Homeland Security Tom Ridge, then serving as Director of the White House Office of Homeland Security, signed a Smart Border Declaration with the Canadian Deputy Prime Minister. The Declaration set forth a 30-point action plan designed to enhance the security of the United States and Canadian shared border while continuing to facilitate the flow of legitimate travelers and cargo. This action plan resulted in initiatives to share information between the United States and Canada related to air travel, including Advanced Passenger Information/Passenger Name Record (API/PNR) Risk Assessments.

An essential goal of the API/PNR Risk Assessment Initiative is the concentration of inspection resources on high-risk travelers while facilitating the movement of legitimate members of the general traveling population. A risk assessment process evaluates passengers arriving into the United States or Canada.

CURRENT HEALTH SCREENING PROCEDURES AT PORTS OF ENTRY AND INFORMATION
SHARING AMONG CDC, CBP, AND OTHER DHS COMPONENTS

As part of CDC's authority to prevent the introduction, transmission, and spread of communicable diseases into the United States, its possessions, and territories, CDC is authorized to isolate and/or quarantine arriving persons reasonably believed to be infected with or exposed to specified quarantinable diseases and to detain carriers and cargo infected with a communicable disease. DHS has agreed to assist CDC in the execution and enforcement of these authorities, primarily in the enforcement of CDC-issued quarantine orders, and through collaboration with other Federal, State, and local law enforcement entities.

HHS and DHS executed a Memorandum of Understanding in October 2005 that details the roles and responsibilities of each Department and agency to mitigate the entry of infectious diseases at the Nation's borders. (within HHS this memorandum implemented through the CDC.) Since the CDC's DGMQ cannot possibly cover every port of entry, successful screening depends on CBP officers having access to simple, usable tools and protocols to identify travelers who may be infected with a quarantinable disease. By the same token, CBP has law enforcement powers to aid CDC in carrying out its authorities and has access to data that CDC needs to perform its public health duties.

HHS will consult with DHS to define steps necessary to obtain information expeditiously when either agency believes there is a public health emergency. The Departments agreed to assist one another in informing the traveling public of potential disease threats, including assisting in the distribution and dissemination of CDC Travel Notices or Health Alert Notices if necessary and as resources permit.

DHS has agreed that its personnel will assist with surveillance for quarantinable or serious communicable diseases of public health significance among persons arriving in the United States from foreign countries, with the understanding that DHS personnel may not have medical training and therefore are not expected to physically examine or diagnose illness among arriving travelers. Surveillance by DHS personnel would generally consist of the recognition and reporting of overt visible signs of illness or information about possible illness provided to them in the course of their routine interactions with arriving passengers, and does not include eliciting a medical history or performance of a medical examination. In situations where a significant outbreak of a quarantinable disease is detected abroad, CDC may request that DHS personnel assist with active surveillance, using a number of methods to assess the risk that individual passengers, arriving from affected countries or regions, are carrying a quarantinable disease. CDC will ensure that a quarantine officer or designated official with public health training will be available to assist in the evaluation of individuals identified through active surveillance.

CDC has statutory authority to require reporting of ill travelers, conduct certain public health inspections of carriers and cargo, and impose certain entry requirements for carriers and cargo that may pose a communicable disease threat. DHS will aid CDC in the enforcement of its statutory authority regarding quarantine rules and regulations pursuant to operational guidelines to be developed by mutual agreement of the parties. Such guidelines will include emergency measures to be taken when a carrier or vessel is determined, after leaving a foreign port, to be carrying a passenger or passengers with a quarantinable or serious communicable disease.

PASSENGERS WITH POTENTIAL PUBLIC HEALTH THREATS AND THE COMMERCIAL
AIRLINES

Under the Aviation and Transportation Security Act, the Transportation Security Administration (TSA) has broad authority to assess and address threats to transportation and passenger security. Under this authority, TSA can direct airlines to deny boarding to an individual identified by the CDC as a threat; this includes individuals identified by the CDC as a public health threat. Based on the request from CDC/HHS, the Assistant Secretary of Homeland Security at TSA may determine that the presence of such an individual aboard a commercial passenger airline flight poses a threat not only to that flight but to the entire transportation system, should the disease spread to other passengers, flights and flight crews, and other modes of transportation used by those individuals.

TSA has a number of options where a person who poses a public health threat may attempt to use the commercial airline system. In the case of last week's incident, as soon as CDC recognized that the individual may have been attempting to fly on a commercial airliner to enter the United States against their CDC advice, TSA directly contacted the Transportation Security Administration Representatives (TSARs) in Europe and International Principal Security Inspectors (IPSI's) world-

wide to inform carriers, embassies, and host government authorities that the infected individual should not board a commercial flight. TSA also chose to use the existing infrastructure of its watch list system. Given the imminent travel of this infected individual, using the existing process was deemed the most expeditious way to alert the airlines to prevent the individual from boarding. At no time, however, was the infected individual identified as a terrorist. TSA has other means at its disposal to communicate threats to airlines immediately and direct them to implement specific security measures, such as the issuance of a Security Directive.

The fact that the introduction or spread of a communicable disease through the transportation system is not necessarily a threat involving criminal violence or other unlawful interference with transportation does not preclude TSA from exercising its authority to address such a threat. The security of the transportation system involves protection of the system from any threat that may disrupt transportation or endanger the safety of individuals in transportation. In the case of biological threats to the transportation system and its passengers, such as the introduction of a communicable disease, it may be impossible to determine whether the source of the threat is intentional human action, human failure, or a natural occurrence. TSA's authority is not limited to dealing only with threats of intentional terrorist acts against the transportation system. TSA is charged with assessing all threats to transportation and executing such actions that may be appropriate to address those threats.

CONCLUSION

In summary, let me restate that DHS will proactively exploit the lessons learned from this incident to strengthen our homeland defenses and response to infected air travelers. We also look forward to streamlining collaboration with HHS/CDC, the Department of State, and State and local public health authorities to jointly combat the growth of global infectious disease threats, including pandemic influenza. DHS apparently had a single point of failure, but that has been corrected and has resulted in structural improvements to border security thanks to decisive action by CBP leadership.

We are encouraged that the U.S.-E.U. information sharing of Passenger Name Records for public health purposes contributed to CDC's efforts to contact travelers who may be at risk for disease transmission. We look forward to strengthening U.S.-Canadian cooperation and communication on API/PNR and have already reached out to continue negotiations. The TSA acted quickly to provide assistance to CDC in this case, and has already begun to explore expeditious ways of communicating "pop-up" threats to commercial air carriers. Finally, my office, the Office of Health Affairs, leads the ongoing efforts to fulfill the Department's responsibilities for Bio-defense, including enhanced biosurveillance, and emergency preparedness and response, in close coordination with our Federal partners.

Thank you for the opportunity to present the Department of Homeland Security's testimony today. My colleagues and I are available to respond to your questions.

Senator HARKIN. Thank you very much, Ms. Spero.

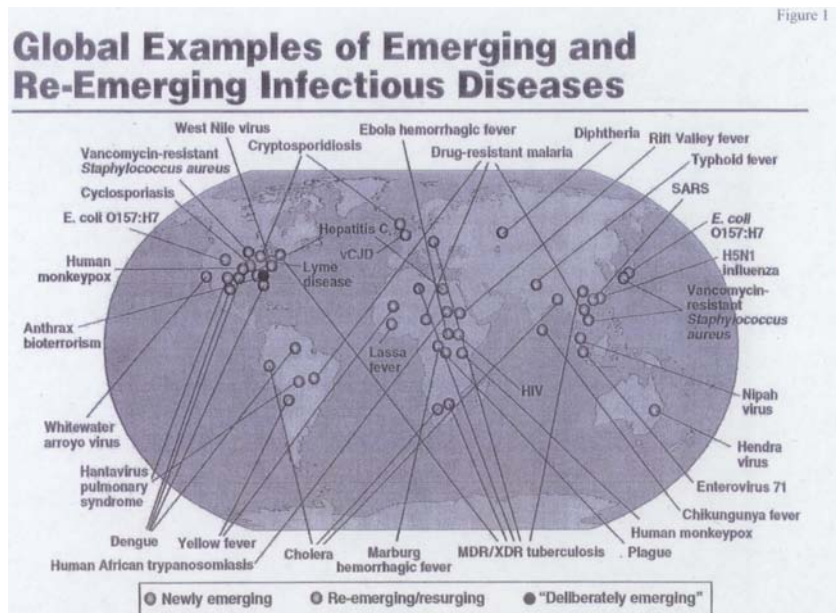
Now we turn to the questions of, just how sick was Mr. Speaker? What is XDR? What's the extent of tuberculosis? What's NIH's role in this? What do we have to look forward to in the future in regards to tuberculosis and this very virulent strain of tuberculosis? That's why we have the Director of our National Institute of Allergies and Infectious Diseases at NIH, Dr. Anthony Fauci, again no stranger to this committee. Dr. Fauci, again please proceed.

STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. FAUCI. Thank you very much, Mr. Chairman, members of the committee. Thank you for giving me the opportunity to talk to you today about the role of the NIH and the National Institute of Allergy and Infectious Diseases in the study of and providing the basis for the development of countermeasures in the form of diagnostics, therapeutics, and vaccines to complement the public health issues that Dr. Gerberding spoke about vis a vis the CDC.

TUBERCULOSIS AND PUBLIC HEALTH

You might recall, Mr. Chairman, that just 15 days ago I showed you this slide at the congressional—excuse me—at the Senate hearing that we had on the NIH budget, in which I testified on behalf of my institute. You might recall that I pointed out to you the constant threat of emerging and reemerging infections, not only the obvious new ones like HIV and SARS or the reemerging ones like West Nile Virus, but also a group of diseases that continue to persist, emerge, and reemerge in the form of multiple drug-resistant microbes. Among those are staphylococcus, malaria, and also, as we mentioned and discussed, tuberculosis, the subject of our hearing here today.



Now, one of the problems with tuberculosis is that we as a community of public health officials and scientists have had relative success over the years. If you look at the curves of tuberculosis in the United States that antedated the HIV epidemic, it was almost a straight line coming down because of public health measures; there were drugs that were effective. It wasn't much resistant, and I'll tell you a bit about a vaccine in a moment.

When the HIV epidemic came, it was really a wakeup call that reinforced for us what we already knew, that the vast majority of tuberculosis can be well contained by the body's immune system, and it generally contains it and it often stays in the latent form. We know that one-third of the world's population is infected with tuberculosis. They're not sick with tuberculosis, but they're infected with tuberculosis.

Senator HARKIN. Repeat that again, Dr. Fauci? One out of every three persons?

Dr. FAUCI. People in the world. Two billion out of 6 billion people are infected with tuberculosis, the vast, vast majority of them in the latent form. There are about 8 million cases per year globally of tuberculosis, about 1.6 million deaths.

Now, getting back to HIV, HIV is a good example of what happens when the immune system is compromised, in this case by the immunosuppression and immunodeficiency of HIV. There are some interesting numbers. Of 40 million people living with HIV, a third are coinfecting with TB. TB is the leading cause of death among HIV-infected people worldwide.

There's an unfortunate relationship between TB and HIV. TB accelerates the replication of HIV and on the other hand HIV accelerates the progression of TB. So with the vast problem of 40 million people living with HIV and the overlapping of HIV and TB, this is a very serious problem that completely antedated the situation that we're talking about here today of someone, healthy, young, not HIV infected, who actually gets infected—we don't know how; likely through travel and exposure—whose disease is latent, but who nonetheless manifests the multifaceted way that tuberculosis can present itself, either in a latent or in active form.

So what about the research endeavors, and why do we have the challenges that Dr. Gerberding mentioned? We have diagnostics that are antiquated. We have not graduated the science of tuberculosis into the 21st century. We've done well. We've been essentially victims of our success. We've accepted diagnostics that are antiquated, insensitive, and slow.

It would have been wonderful when that patient first went to a physician and that culture came back that you could have had a point of care molecular diagnosis, A, of TB, and B, of whether or not it was sensitive or resistant. We don't have that.

The drug regimens are complex and lengthy, for a number of reasons. This is a complex microbe and, as Dr. Gerberding said, it grows slowly. Microbes that grow slowly generally need to be treated for extended periods of time. That's one of the big stumbling blocks with tuberculosis. Under normal circumstances it requires 6 to 9 months of therapy. Patients generally feel good soon after therapy is started. Often they don't continue the therapy—a perfect setup for the development of multiple drug-resistant tuberculosis, namely resistant to the first line of drugs.

You can compound that problem when someone comes in with multiple drug-resistant TB and it isn't recognized as that and you treat them inappropriately. You can then push the spectrum to extensively drug-resistant TB, and this is a problem that has been emerging over the past several years.

Vaccine. We've had a vaccine for a century for TB, BCG. It has effectiveness in preventing infection like the meningitis we see in children. It is considerably ineffective in preventing the pulmonary tuberculosis characteristic of infections in adults.

So what are we doing at the NIH? We have the same research agenda that we've had in the past, fundamentally basic research as

our matrix. But we're doing things differently. The pharmaceutical companies have been reluctant over the years to get involved in the development of countermeasures, for obvious reasons. This is not necessarily recognized as an area of interest. It has been almost forgotten.

So we've partnered with the public—excuse me—with the private sectors, to make drugs and vaccines. We have now the first vaccines in trial in 60 years. It just goes to show you—a problem that kills 1.6 million people a year and we've had no vaccine trials until recently. Now we have 10 vaccines in the pipeline, five diagnostics, and 10 new therapies.

This is a picture of the research agenda which we have been working on. We have shared it with our colleagues on the outside, inside the NIH, and have received a considerable amount of help from our colleagues at the CDC. This morning, we have put this live on the NIAID web site. It outlines the six basic approaches towards the research agenda: diagnostics, therapeutics, basic biology, molecular epidemiology, host factors, and prevention, including vaccines.

So finally we get back again to something that I mentioned the last time I testified before you just over 2 weeks ago: that the extraordinary capability of many microbes to persist, emerge, and re-emerge is an inherent part of their molecular makeup and their evolutionary capability. How do we balance that? We balance that by the public health measures that Dr. Gerberding mentioned. We balance that by the development of countermeasures in partnership with industry, as well as the biomedical research agenda. This is something that we have been actively pursuing and will continue to pursue, so that there will be medical countermeasures to complement the work that you've heard of from Dr. Gerberding.

I'd be happy to answer any questions, Mr. Chairman.

Senator HARKIN. Dr. Fauci, thank you very much.

We'll start with questioning. I'll start, then Senator Gregg, and then Senator Brown.

First I'm going to start with Ms. Spero because I think we might be able to summarize this very rapidly. The CDC put out an alert to you on May the—

Ms. SPERO. The 22d.

Senator HARKIN. May 22. Now, inform us. This goes through the systemwide, to all of the inputs, all of the places where people would come across the border. But I was told that this only identifies someone who uses a passport. Is it not so that this person who came across the border from Canada didn't show his passport, but only showed a driver's license?

Ms. SPERO. If I could clarify that, Mr. Chairman. CDC did not put out an alert. They came to us and asked us to do something in our system. They have—we have good relationships with CDC in our ports of entry and they came to our Atlanta office and they were able to put an alert in a system that we use that contains millions of records, that alerts our officers to various potentially risky passengers or travelers.

Senator HARKIN. But tell me, when they did that on the 22d what was the information given to your border people?

Ms. SPERO. The local people?

Senator HARKIN. Yes. What would have come up on the screen, for example? What would it have said?

Ms. SPERO. We actually put in an alert, and what the screen said on the alert was: "If you see this individual"—and then subsequently, the next day we put an alert on Sarah Cooksey, his fiancée at the time—and it said: "Place mask on subject." It said: "Refer to secondary. Place mask on subject. Place in isolation, well-ventilated room if possible. Subject has multiple resistant TB, public health risk." Then it gave the name of the Public Health Service doctor and contact him 24 hours, and it gave two telephone numbers for him. So the instructions were very clear.

Senator HARKIN. Okay, that's what came up on their screen?

Ms. SPERO. That's correct.

Senator HARKIN. Now, did Mr. Speaker have to use his passport or did he just use a driver's license to come across the border?

Ms. SPERO. He was not required to, but my understanding of the event is that he did show a passport.

Senator HARKIN. But he was not required to?

Ms. SPERO. Correct. If I could take an opportunity, on our land border with Canada travelers are not always required to show documents. That's the reason that we are so anxious to implement the Western Hemisphere Travel Initiative, which will make such a requirement mandatory.

In this particular case, the officer did get I believe both passports from Mr. Speaker and Ms. Cooksey.

Senator HARKIN. So he did show his passport, even though he didn't have to? If he hadn't shown his passport, then obviously nothing would have even come up.

Ms. SPERO. That is the problem. We use a vehicle license plate reader, and in this case—but that would not have triggered this particular alert.

Senator HARKIN. But the Border Patrol person that was there actually saw this information on the screen?

Ms. SPERO. Yes, sir.

Senator HARKIN. Did not follow that?

Ms. SPERO. Correct.

Senator HARKIN. I see. I just wanted to get that clear on the record.

TIMELINE

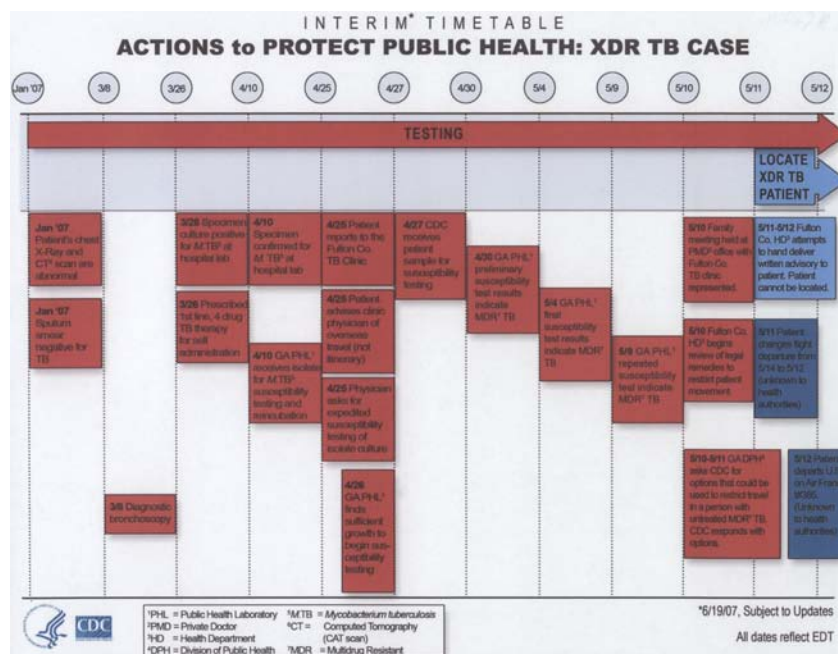
Dr. Gerberding, as I mentioned to you before the hearing, I am somewhat perplexed by the fact that on May 17—you've told me it was May 18—that CDC was notified by the Fulton County officials that Mr. Speaker didn't just have the multiple drug-resistant strain, but that he had the extremely drug-resistant variety. CDC was notified either the 17th or 18th. You can tell me what time of the day. I don't know.

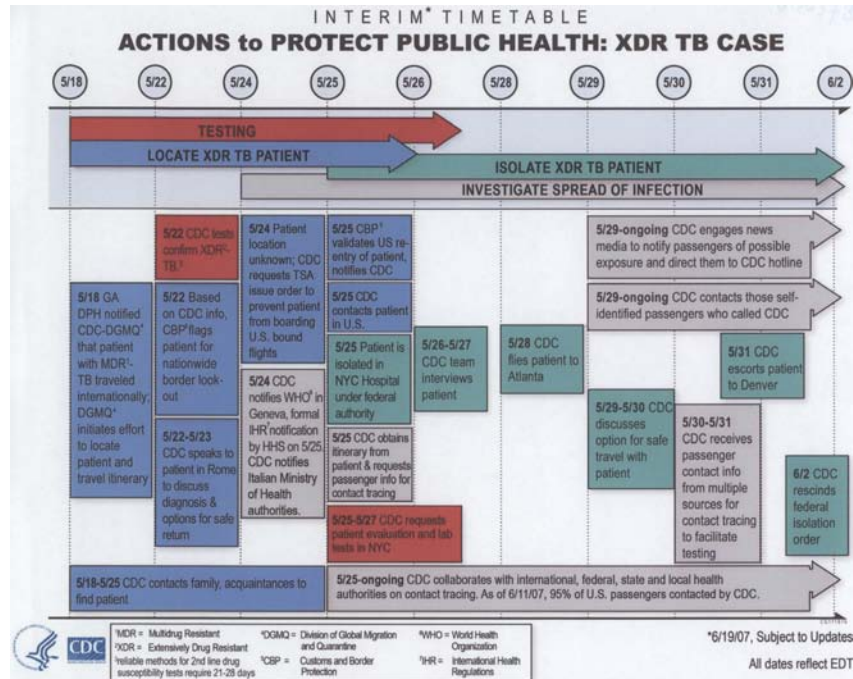
But it wasn't until May 22 that the CDC informed the Atlanta office of the Customs and Border Patrol, and then it wasn't until the 25th until CDC informed the WHO. My question is, what happened on the 19th, the 20th, the 21st, up to the 22d? What was going on?

Dr. GERBERDING. Let me provide some perspective on that. CDC learned on the 18th from the Georgia Health Department that the

patient may have traveled internationally to Greece. So it was not the 17th. It was the 18th. But there have been several timelines that have gone through various stages of validation, so you may just have gotten information a bit earlier before we were actually nailing down the processes. If we have any updated timeline information, you'll be getting it. It takes a long time to patch these things together.

But it was the 18th that we learned that this patient, who at that time had drug-resistant tuberculosis, MDR TB, was likely traveling in Greece. Timeline, current as of June 19, 2007.





Senator HARKIN. Excuse me for interrupting. I was told that you were told that he had XDR.

Dr. GERBERDING. We did not learn about XDR until the 22d. That was the day at which the CDC laboratory had the results from our own testing of his isolate in our lab, which is really the reference lab for the State of Georgia for this kind of testing. So we did not know the patient had XDR TB until May 22.

Senator HARKIN. But you knew he had MDR on the 18th?

Dr. GERBERDING. Correct.

Senator HARKIN. At least had MDR.

Dr. GERBERDING. So let me describe what really was happening between the 18th and the 22d because I think that is important.

Senator HARKIN. There's a big gap in there.

Dr. GERBERDING. Yes. Let me explain. So if you're in the situation of the quarantine officer at CDC, you get a call that says there's a patient with tuberculosis, drug-resistant, traveling in Greece. That's the first information you have about the who and the what it is that we're supposed to be doing. So that's the marker to begin a case investigation.

We can't just call the world and say there's an itinerant tuberculosis patient on the loose. We have to first validate this. For the sake of all of our citizens, we can't overreact when there are issues of civil liberties and personal rights engaged. So you have to investigate, and that's what really went on for the next couple of days.

Senator HARKIN. Let me clarify something here. I thought we knew he was out of the country on the 18th. I hate to get so par-

ticular on days, but there seem to be gaps of 2 and 3 days here where nothing seems to have been done.

Dr. GERBERDING. Let me explain again. On the 18th, this was the first official notification to CDC that we had an MDR tuberculosis patient that was believed by the county health department to be traveling internationally, likely in Greece.

Senator HARKIN. Right.

Dr. GERBERDING. So that was the 18th.

Senator HARKIN. Yes.

Dr. GERBERDING. That was our start time to initiate an investigation. We have to go through the whole process of who is this, what is his situation, how do we corroborate that he has MDR TB, where could he be. We contacted the airlines where the health department believed he may have traveled. We were in communication with the health department: Please send the clinical records, please get the contact information, please help us piece together where could he be, why did he go there, how can we validate before we take legal measures to interfere or we send our counterparts at Homeland Security into action.

So this is, as you know, part of public health. It requires an investigation. We can't just act on presumption. We can't act on first indication. We have to get our disease detectives to work, dig into this, and figure out what's going on. That's what went on.

One of the confusing aspects of this is that the airlines searched their records to determine if the passenger actually left Atlanta on Delta Airlines, as he had planned to do to go to his wedding. We looked 3 days before that, we looked 3 days after that, and Delta had no record that this patient had flown out of Atlanta. The reason for that was because the patient had, first of all, switched his flight earlier, 2 days after he had had the conversation with the health department, and second, when he switched he was on Air France, and Delta can't see into Air France passenger manifests, a fact that we did not know ahead of time.

So on the 22d when we learned that the patient had XDR TB, we felt it was appropriate for us to contact CBP and to try to see whether or not our security measures could be engaged to help identify the patient as he entered the United States. So we in retrospect wish that we had sent all kinds of alerts through the travel system on the 18th because that may have made a difference, but I think, looking at this as we would look forward into the scenario, we would really want to have some facts and information together before we took these kinds of actions to put a citizen on the terrorism watch list or to in any other way interfere with their civil liberties without due cause.

So we were balancing. We've got to find somebody who could pose a public health risk, but we also have to be sure we're right and that we're being fair to the individual involved.

DEGREE OF CONTAGIOUSNESS

Senator HARKIN. Well, again, time. I understand all of that, but you did know by the 18th that he had, again he had at least MDR? You knew that on the 18th?

Dr. GERBERDING. We were told that he had MDR TB and we believed that to be accurate based on other laboratory information.

Senator HARKIN. On the 18?

Dr. GERBERDING. Yes.

Senator HARKIN. Well now, it would seem to me that would compel you then to activate watch lists immediately so that this person is not traveling. But yet you—

Dr. GERBERDING. If we did that we would be putting an awful lot of people on watch lists across our country. Again, we have to look very carefully. Lots of people have MDR TB. We can't put every one of them on a watch list. In this case, we had reason to believe that he was traveling internationally, so we checked to see, was that true, was he actually traveling internationally.

You know what would happen if you get put on a watch list. The next time you would try to go to the airport, you would likely have to spend a great deal more time in the security line. So these things have to be done in a way that represents thorough and comprehensive investigation of all the facts of the case before we were prepared to take that step. Now, this is part of our after-action. We have to go back and say, well, you know, should we be more aggressive about initiating the stop in a situation like this and err on the side of isolating someone using a Federal order or putting them on a watch list before we've done the investigation to be sure that was absolutely essential under the circumstance.

Senator HARKIN. Well, I guess I'm a little confused. I understand what watch lists are and why you have to be careful. But here's a person with a multiple drug-resistant tuberculosis. You've identified this person. You knew that he may be traveling. Fulton County officials told you that. Are you telling me that that's not enough to put someone on a watch list? You mean there's a lot of people running around this country with MDR tuberculosis that you know about that are perfectly capable of getting on airplanes?

Dr. GERBERDING. No, sir, because the vast majority of people diagnosed with tuberculosis cooperate with their local health officials and don't fly on airplanes. What was different about this case is we had a patient who for very compelling reasons chose not to follow the advice that was given to him. But we have to—it's a balance. We're trying to say we've got to protect the public here, we've got to protect the other passengers on these planes or the other people at risk. But at the same time, we have to respect the fact that an individual deserves due process. We have a duty to get the science. We have a duty to document the rationale for taking a step that really imposes a restriction of civil liberties.

Senator HARKIN. Again, tell us again: How contagious was he?

Dr. GERBERDING. Well, contagious at that point in time was a question mark. When he was diagnosed, he had tests of his respiratory secretions. Those tests grew the bacteria in the laboratory. That's how we were able to diagnose the TB and drug resistance. But when you took the same specimens and looked at them under the microscope, you couldn't actually see the TB bacteria. That implies that, while he must have bacteria there since the culture was positive, there's not very much of it, or we would be able to see it on the sample that we looked at under the microscope.

The term for this is "smear-negative," meaning you've smeared some of the respiratory secretions on the slide, it's negative for the appearance of the bacteria, but it's culture-positive. So smear-nega-

tive, culture-positive patients generally pose a lower hazard of transmission, but it's not zero.

Senator HARKIN. What is it?

Dr. GERBERDING. Well, it depends on how long they're in contact with someone and what kind of air circulation surrounds them.

Senator HARKIN. Say on an airplane that's flying several hours?

Dr. GERBERDING. If you were on an airplane with a person like this for more than 8 hours and you were seated in two rows in front of and two rows in back of that patient, there would be an increased risk that you could be exposed. Those are the people that we're concentrating our investigation on.

But a very important point here and one that is coming out now in the news, is that the patient is relatively non-contagious. I hesitate to use any of these terms. If the patient is smear-negative, culture-positive, he could transmit it to people under certain circumstances, and overall about 17 percent of the tuberculosis that we see in the United States comes from people who are culture-positive and smear-negative. So it's not a zero risk. I think that's a very important point.

Senator HARKIN. I'm going to yield. I know other Senators want to get involved.

But it just strikes me as odd that the CDC has at least a couple of aircraft capable of transporting Mr. Speaker from where he was back to Atlanta and on to Denver, but you say that you didn't want to do that because they don't have isolation units in the aircraft. But you're telling me that he could get on an airplane with 300 and some passengers and maybe only the people in two rows in front of him or in back of him are in any danger.

Well, if that's the case then the pilots in a Gulfstream 3 would not be in danger. He's sitting in the back. They're not exposed to him. So the question I have is, why wasn't that CDC aircraft used for that purpose?

Dr. GERBERDING. At the time that we were making the decisions about flying him, we didn't know how infectious he was. The tests that I referred to were done back in March. They hadn't been repeated recently in the time where he was traveling. So he could have been much more infectious, in which case there would be a much greater risk to people on the air travel.

We look at how infectious is he, we look at how bad is this organism, and we look at how many vulnerable people are around that he could present a hazard to.

Senator HARKIN. I thought you knew that at that time from his smear-negative.

Dr. GERBERDING. We knew he was smear-negative in March. But his sputum had not been examined recently. So it wasn't until he was in Bellevue after he had come home that he had repeated tests of his sputum done that showed, thankfully, he was smear-negative. That's when we used the CDC aircraft to fly him on a short trip back to Atlanta.

Senator HARKIN. Then to Denver.

Dr. GERBERDING. Then to Denver. The patient's health insurer coordinated the transportation of the patient to Denver using their air medical contractor.

So we had information when we used the CDC plane to tell us that he was smear-negative. We didn't have that information when he was still in Europe and had been at least 2 months without any treatment for his tuberculosis. So in retrospect we may have made a different decision, but at the time we really had to protect everyone who could be at risk from this deadly bug.

Senator HARKIN. I have a couple more, but I've used much more time than I should have and I want to yield to other Senators.

I understand we have Mr. Speaker up now. Is that the case? Can you hear us, Mr. Speaker?

Mr. SPEAKER. Yes, sir, I can.

Senator HARKIN. Fine. I'm glad we got the bugs worked out. You'll be on our second panel. We have just finished our witness list and now I'm yielding to Senator Gregg for his questions.

NOTIFICATION PROCEDURES

Senator GREGG. Thank you, Senator.

When did you talk to him in Italy, what day? What day did you talk to him when he was in Italy?

Dr. GERBERDING. It was about 12:30 a.m., May 23, Rome time, so it would be about 6:30 p.m. here on May 22.

Senator GREGG. Is there a protocol with Italy? Let's say it had been an Italian citizen coming to the United States and they talked to us. Would there be a—and they'd been talking to their citizen in the United States. Is there a protocol that either goes through the WHO or that's bilateral, that would have allowed you to take action which would have contained his movement in Italy, since you had no way to get him back to the United States that you were aware of because you had no plane available and he shouldn't be traveling commercial?

Dr. GERBERDING. It was the middle of the night when we talked to him and we continued conversations with him the next morning. We were able to contact a TB expert who had knowledge of the chest hospitals in Italy so that we would be able to tell him where to go. This individual worked at the ministry of health in Italy, but she was also a former CDC employee, so we knew how to contact her directly. She actually went to his hotel early the next morning to see if she could talk to him in person and try to facilitate his medical evaluation and determination of his need for isolation. But he had already left.

Senator GREGG. But you're saying that you couldn't—there's no authority that you could contact? I mean, an individual who's a doctor there is obviously appropriate to refer him to, but on the 22d it appears you knew that he was potentially a very significant threat to people around him. But there's no formal protocol, I take it, with other nations that would allow those other countries to call up the head of CDC in Italy and say, this person should be contained in some sort of quarantine capability?

Dr. GERBERDING. There are international health regulations that facilitate this kind of communication and we are in a protocol environment where you notify the World Health Organization that you have a patient who may present a health threat and you can notify the minister of health in the affected countries, and CDC initiated that process by contacting this minister of health representative in

Italy to make an assessment of how much further the notification needed to go.

If the patient at that point——

Senator GREGG. Well, if I can just break in here, doctor, because my time is limited, I guess. But the issue is this. You knew you couldn't get him back because you knew you didn't have a plane that could bring him back and you knew he shouldn't fly commercial. Shouldn't there have been the capacity to immediately get action in Italy by using Italian authority to contain him in Italy, rather than simply have it be—have it still be on his goodwill that he not move, since he'd obviously shown he was going to move internationally?

Dr. GERBERDING. You're making exactly the point that we have learned from this, is that when a patient has demonstrated unwillingness to cooperate we cannot give that patient the benefit of the doubt any more. We should have initiated——

Senator GREGG. The second part of that question is, does that protocol exist? In other words, do you have the capacity to pick up a phone and talk to somebody in Italy or China or Japan or other reasonably—or developed nations generally, and maybe even undeveloped nations, and get an agreement and an immediate action event when you have somebody who you think is a risk to their, obviously, their society and to people that they're traveling with?

Dr. GERBERDING. Absolutely, and we do this on multiple occasions for many other infectious disease circumstances frequently. So yes, we call the minister of health, they have a TB control office, a very fine program in Italy, and they can take the appropriate steps.

Senator GREGG. But that authority wasn't used?

Dr. GERBERDING. We did not make that authority decision initially. We contacted someone from the health ministry. We said, assess this; can we find a way to help this patient get to isolation in Italy without imposing a law enforcement standard around him? The director of communicable disease control in Italy was also notified by e-mail.

We, in retrospect, should have done that. He chose not to cooperate with us and we made a mistake in not giving—we gave the patient the benefit of the doubt and in retrospect we made a mistake. When the patient was contacted in Rome, the patient assured CDC that he would not continue to travel until further arrangements could be made.

INFECTIOUS DISEASE THREATS

Senator GREGG. I think the almost bigger issue, although this issue is obviously significant, especially for people who were traveling with him on those airplanes, but the bigger issue is the potential threat this represents to world travel and to commercial activity and to different countries. I mean, this individual chose consciously to move with an infectious disease. It's potential that a terrorist might choose to infect themselves and move with an infectious disease.

Is there any capacity at all to deal with that type of a situation?

Dr. GERBERDING. Well, certainly there is and in a situation of a suspected terrorist we would be able to immediately engage law en-

forcement without anybody questioning the validity of that. I think we have to acknowledge that with infectious diseases we cannot hermetically seal our borders. We can have people moving across borders with infections who are asymptomatic. We can have people moving across our borders with diseases that don't manifest symptoms that would be picked up at our quarantine stations or by our Customs and Border Patrol, no matter how well trained they were. Right now we only have quarantine officers in 20 airports around the United States and we have I think more than 240 crossing areas where people can come across our borders.

So there are—actually, there's 474 ports of entry into the United States. We do not have quarantine offices at all 474 ports, nor will we ever. So if the question is can someone with an infectious disease ever make it into the United States and pose a health hazard, the answer is absolutely yes.

Senator GREGG. Obviously this is where Dr. Fauci and his team become so important, to try to develop responses to that sort of an event. Certainly we've been—

Dr. GERBERDING. I was just notified also by my colleagues that actually CDC did contact the minister of health, the ministry of health in Italy, on the 24, which is the day after the patient contacted us. So we did make an official notification to initiate the process that you are describing.

NO-FLY LIST

Senator GREGG. One last question if the chairman will indulge me, and that's this. In one of the notes that was given us, at 3:35 on May 24 CDC gave DHS Mr. Speaker's information, and according to this note the Terrorist Screening Center, which administers the no-fly list, determined that Mr. Speaker did not qualify for the list because he was not suspected of a crime.

I hope that's not what the decision was. I hope that's not the position, because dealing with terrorists you just can't wait for the crime. The whole theory that we've supposedly been functioning under relative to responding to terrorists is that you've got to find them before they commit the crime. This is not a post-crime event. It's the big problem we've had with changing the culture at some of our law enforcement communities, because they're always crime-related, to get them to anticipate.

Is that the policy of the Terrorist Screening Center, that if somebody hasn't committed a crime they're not put on the watch list?

Dr. GERBERDING. Absolutely not. The patient did get put on the watch list. It just required some clarification for a very short period of time that day while people verified it, just like we at CDC had to verify from our legal counsel that it was okay to put someone on the list that involved distributing their personal information around the world. But that was a matter of a couple of hours, not a matter of days.

Senator GREGG. But was the initial response from the Terrorist Screening Center that they couldn't put him on the list because he hadn't committed a crime?

Dr. GERBERDING. The initial response was, let's make sure. I think as our agencies have reviewed this we've made it crystal-clear that absolutely a person who poses a public health threat can

be put on that list and we've streamlined the process for getting them there.

Ms. SPERO. If I may clarify, that was the responsibility of the Transportation Security Administration, another agency within the Department of Homeland Security. Technically, I think the issue was around the name of the list and the process for putting him on the list, not so much the crime aspect, but that he was a public health risk at that time, not a terrorist risk. So the TSA Administrator used his authority to put—to identify him on something that is an adjunct to the watch list.

Senator GREGG. Does it have the same status as the watch list as far as—

Ms. SPERO. Yes, that would be the same process, yes.

Senator GREGG. Distribution?

Ms. SPERO. Yes, sir.

Senator GREGG. Thank you.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Gregg.

Again, I want to make sure that Mr. Speaker is able to hear the proceedings. Are you hearing the proceedings, Mr. Speaker?

Mr. SPEAKER. Yes, sir, I am.

Senator HARKIN. Very good. Just to set the stage for you, I don't know how much you know. You're a little bit at a disadvantage. We had hoped to have a visual setup. But we have had Dr. Gerberding, the head of the Centers for Disease Control and Prevention, and Dr. Anthony Fauci, who's the head of the Infectious Disease Institute at NIH, and Ms. Spero, who is the—let me get your right title again here—Deputy Commissioner of United States Customs and Border Protection.

So we've had their testimony. We've had some questions from both myself, Senator Harkin, and from Senator Gregg, you just heard from, from New Hampshire. Now I'm turning to Senator Brown from Ohio for his questions.

STATEMENT OF SENATOR SHERROD BROWN

Senator BROWN. Thank you, Mr. Chairman. Thank you for the courtesy of allowing me to sit in on this.

Dr. Fauci, thank you. Dr. Gerberding and Dr. Castro, thank you for being here and the good work you do.

I think it's safe to assume that most Americans prior to this incident never heard of MDR TB or XDR TB. Most Americans think tuberculosis is a disease of the past. As you point out, Dr. Fauci, it decidedly isn't. In our country—Dr. Fauci pointed out that one-third of people in the world carry the bacteria, the tuberculosis bacteria. Some 10 to 15 million Americans, it's estimated, carry that. Some 600, 700, 800 Americans every year most years in the last decade have died of tuberculosis. Some 1.6 million people around the world. In the country of India I believe about 1,000 people a day die from tuberculosis.

So we know the problem, and I think that we also know that tuberculosis is an old, old disease, as old as recorded history perhaps. But we need to understand that MDR and XDR TB are entirely human-made, that they result from patients with normal TB not receiving complete treatment, most often due to weak programs, in-

adequate drug supplies. We have failed to provide the basic elements of dealing with that problem.

I think one lesson from this today from this whole unfortunate incident is that XDR TB, MDR TB and XDR TB, is a marker of decades of our chronic underinvestment in tuberculosis efforts domestically and globally, and this doesn't come as a surprise to those of you that have worked on this for so many years. Underresourced programs in the United States, much of the world, paltry investment in new diagnostic drugs and an ineffective vaccine, and recently flat-lining domestic control efforts.

We've been down this road before 15 years ago, a little more than that, in the late 80s. The underfunding of TB control in the 1970s and 1980s led to a terrible, terrible outbreak of drug-resistant TB in New York, as you remember, costing \$1 billion to taxpayers because we hadn't spent the tens and hundreds of millions to do what we needed to do for our public health infrastructure. I'm hopeful that we learn from that a little less expensively this time than that.

But I think that the point of all of this is if we're going to deal with multi-drug-resistant TB, if we're going to deal with the even more serious XDR TB, we need to do way better with CDC and NIH and public health authorities all over the country. I know you already know that and believe that and understand that.

We have introduced, I have introduced with Senator Kennedy and Senator Hutchison, our Comprehensive TB Elimination Act, S. 1551, which will provide, authorize \$300 million for domestic—I understand we spend about a third of that, a little more than that—for domestic TB. Senator Boxer has her legislation for global TB control.

But if you, Dr. Fauci and Dr. Gerberding, now that I've done my commercial for the bill that we're working on, if you would sort of share with us what this funding—what you would be able to do which will help to eliminate TB in this country and what that would mean in terms of ultimately XDR and MDR TB and where we go, if you would.

TB CONTROL

Dr. GERBERDING. Let me just start and say thank you. You are absolutely right, we are aware of a great deal of media interest in this case for obvious reasons. But I wish we had had the same degree of media interest the last time we were in the Senate testifying on XDR TB.

We really have a situation in the United States where our TB control programs have been receiving the same amount of money year after year, at a time when the threat of tuberculosis is actually increasing, in part because of the XDR and the MDR component. But also that stable funding represents a decrease in the States' capacity because the cost of doing TB control has obviously gone up in the interim, even if nothing else changed.

So the resources that are being proposed would allow us to think of better ways to modernize and streamline our programs. It would allow us to do a better job of contact tracing. It would allow us to initiate better diagnostic testing. There are more modern methods

of doing TB testing that we're not able to deploy effectively in our health departments today because of resource limitations.

More importantly, I think they would allow us to strengthen our activities with international immigrants and refugees who come into our country. In the United States, even though we have a record low number of TB cases, a greater and greater percentage of them are arriving through people who are immigrating to our country. So we need to strengthen our borders. I think that's a theme of this whole conversation today.

CDC used to have hundreds of people working in its quarantine stations at many, many points of entry. During the last few years we've been able to increase the number of active quarantine stations from 8 to about 20, but we are a long way from being able to support our Customs and Border Patrol people with the kind of medical support we're going to need in this modern world.

So we appreciate the acceleration and the support through the preparedness resources and the homeland security resources. But TB is a special focus area and we need to do more. We've certainly learned that from this experience.

Dr. FAUCI. In the same vein, Senator, we appreciate greatly the effort and the leadership you've shown with your bill. As you explicitly say in the language when you talk about the kinds of research that is needed, everything from basic biology up through and including the development of a vaccine are specifically mentioned. As I alluded to in my previous comments, it is critically important to get the field of tuberculosis into 21st century science, starting off, just as Dr. Gerberding said, with the research related to getting what would ultimately be a point of care type diagnosis, where you can molecularly not only pinpoint the microbe, but by looking at its genetic configuration and the expression of its genes you'd be able to already tell right from the get-go that you're dealing with something that would be predictably multiple, if not extensively, drug-resistant. That is critical to the kinds of public health measures that the CDC and others are responsible for.

The same holds true for therapies. We really do need pipelines. If you look at the drugs that have been developed for TB, the last good one was when I was in—when I was in medical school. Before I was in medical school was the last one that was approved. When you have a disease that's killing 1.6 million people a year, that's just not good enough.

Then finally, having relied on a what is generally agreed upon as an ineffective vaccine for adult pulmonary tuberculosis, we have to use the resources from your bill to be able to get a cadre of investigators to get involved with industry in developing a vaccine.

So in summary, we're very greatly appreciative of your efforts in that.

Senator BROWN. Thank you.

As we see us spend \$2 billion a week in the war in Iraq and give tax cuts to the wealthiest 1 percent of people in this country and we see how woefully, this hearing shows how woefully we underfund our public health system, I hope we're learning something from all of this.

Thank you.

Senator HARKIN. Thank you, Senator Brown. Thank you for your leadership in this area. You're absolutely right, we have been underfunding public health for a long time. We've been talking about that on this subcommittee for many years. We've finally got facilities at CDC, but obviously I think we need to do more to beef up our public health system.

DRUG RESISTANCE TESTING

I have about three further questions, Dr. Gerberding, and they all revolve around the uneasy feeling that I have that between the period of time when CDC was notified by Fulton County—and we're going to have Fulton County in the next panel, Dr. Katkowsky, I think his name is, who's the head of it—I have the uneasy feeling that once CDC was notified he had XDR, not MDR, XDR, on May the—CDC was notified on May 18—I had 17; you said 18; that's fine—that Fulton County was notified he had the XDR strain—

Dr. GERBERDING. No, sir. CDC made the determination of XDR TB in our laboratories on the 22d.

Senator HARKIN. When did Fulton County public health officials determine he had XDR?

Dr. GERBERDING. They don't have the capacity to do that because the State lab doesn't do the extensively drug-resistant tests that we're able to do at CDC.

Senator HARKIN. I'm sorry, because I was told that Fulton County had notified you on the 20th—I'm sorry, on the 18th, that he had the extremely drug-resistant variety. That is not the case?

Dr. GERBERDING. That is not the case.

Senator HARKIN. I understand. Then that clears that up. Then you then took that—then you over the next few days then determined he had the extreme?

Dr. GERBERDING. Let me just explain real quickly how this works. When a patient is diagnosed with tuberculosis, a clinical lab looks at the specimen and says, yes, there's tuberculosis here. Generally the sample goes to the State lab. The State lab tests for drug resistance, but it takes a long time. When they see signs that it may be drug-resistant, very often they communicate with CDC.

We take the sample to our labs and begin to do the more sophisticated tests that can't be done in a regular State lab. So our laboratory on the 22 confirmed that the patient had XDR TB.

Senator HARKIN. On the 18th you knew that he had MDR.

Dr. GERBERDING. Correct.

Senator HARKIN. I still get the uneasy feeling—excuse me—that between the 18th and the 22d—I thought it was 5 days; 4 days—that really not much happened and that there was some either confusion or running around in circles or something happening at CDC. Sorry to have to say it that way, you know, because I don't see—

Dr. GERBERDING. Well, I have to tell you that's not the case. There was a very hard-working quarantine officer and his teammates who were hour by hour taking a number of steps to investigate this. They were trying to locate the patient. They were working with the health department and the patient's family to try to locate him.

On the 21st they participated in a very long meeting at the health department to try to pull all the data together and understand where the patient could be. They were contacting the patient's family. They were searching the Internet for information: Where were weddings held in Greece, where could the patient possibly be? They were on a detective hunt to try to figure out, did he leave the country, is he in Georgia, did he go someplace else, did he elope, where was this patient and what was his status?

NOTIFICATION RESPONSIBILITIES

Senator HARKIN. When did you or when did the people at CDC know that his father-in-law was at CDC and was in fact a TB researcher? When was that known to you?

Dr. GERBERDING. Well, I didn't know about it until after the patient was on his way home. Dr. Castro here is the supervisor of our tuberculosis division at CDC and he probably knew that earlier, and I can verify with him. But the important question is when did the quarantine officer who was in charge of this investigation know, and he did not know that early on in the course. We can find out for you exactly when that information became known to the person who was conducting this investigation.

Senator HARKIN. Would it be too much to assume that Dr. Cooksey, I believe his name is, had knowledge that Mr. Speaker had MDR, at least MDR, at the time that Mr. Speaker traveled out of the country?

Dr. GERBERDING. I believe that would be correct, based on what I've heard. I can't validate that because I haven't asked Mr. Cooksey that question. But based on his participation in family discussions on the 10th, he is likely to know that information. I think the health officer can validate that he was completely informed of that.

Now, if he knew that independent of his participation as a family member and when he knew that, I would have to go back and check.

Senator HARKIN. Well, I guess the question—I don't have Dr. Cooksey in front of the panel here, but we may reach out to ask him this question—is, again I ask you, what is the responsibility of someone like that, who is a researcher, who knows what MDR is, and does he have a responsibility to notify CDC of this situation?

Dr. GERBERDING. You know, this is exactly why we are conducting the internal review and exactly why we've asked the inspector general to assist us, because here's a man who's got two compelling responsibilities, the responsibility as a health professional and a CDC employee and his responsibility as a family member and a father of the bride. How that conflict or potential conflict was adjudicated is something that we need to carefully review, and I believe the best way to do that is not only through our internal mechanisms, but also to be sure that we have an objective perspective from the inspector general. So we agree that that needs to be assessed.

PLANNING

Senator HARKIN. I appreciate that.

Last again, the idea of planning. As you have pointed out, most of your experience has been with patients who are compliant. But obviously, I would think once in a while people pop up who won't be compliant, for one reason or another. Have you had, CDC at any time in the past run any kind of trials, tests, to test the system? Say that someone popped up who was noncompliant and began to travel with some virulent infectious disease. Had those kind of tests been run before through your operation?

Dr. GERBERDING. Absolutely. We just in the context of pandemic influenza, have been exercising both around tabletops with media as well as around actual functional exercises at CDC. One of the key areas in these exercises is quarantine and isolation authorities, how can they be utilized in the context of a pandemic.

The issue in the pandemic that's come up, however, for us is again that keeping people out part of quarantine and isolation. We have not yet exercised what about a U.S. traveler with pandemic flu who chooses to travel internationally and how we would go about fixing that. But we will be exercising exactly on that point imminently, because obviously we have learned that.

I think where we would like to focus our exercise attention in this context is with the World Health Organization and the countries. The international health regulations are due to be enforced beginning June 15. They're wonderful regulations, but there's no operational planning around them, and this is going to be the perfect case study for us to sit down with the affected health ministries and the TB officials at WHO and say: Great ideas, but how are we going to create operational and tactical plans?

Every country's going to have to come to grips with the same things CDC did: How do we keep people from going, how do we find out where they are, how do we handle them when we need to isolate them in someone else's country, and who pays?

Senator HARKIN. I appreciate that. But again, I repeat for emphasis sake that on the 18th you were notified that he had multiple drug-resistant TB. Border Patrol was not notified until May 22. He was not placed on the no-fly list until 2 full days later on May 24. Again, with the rapidity of world travel today, it seems to me that this timeframe should have been collapsed to just a few hours.

Dr. GERBERDING. Senator Harkin, in retrospect I would absolutely have acted much earlier. But when we were looking at it through the prospectoscope we really felt we needed to get the science and the evidence and the clinical information together before we took those steps. I think we can do that faster. I think we should have done it faster and I think we'll be able to accelerate this next time.

In retrospect, that was a mistake and I wish we had done it differently.

Senator HARKIN. So you can assure us that through your internal reviews at CDC that you are going to take a look at this, what happened, and to take steps necessary to ensure that in terms of a noncompliant individual in the future that you can assure us that you will put programs in place, procedures in place, to collapse a time frame like that?

Dr. GERBERDING. Senator, I have to say that this makes me sad. I have always had good relationships with my patients and I admit that perhaps I am too optimistic about what people will do. But in this situation we should have recognized that if the person left against medical advice in the first place that by definition means he's unlikely to be cooperative there on in, and that should be an indicator to take more aggressive action.

Our systemic issue here is constantly giving the patient the benefit of the doubt and failing to use the most aggressive measures earlier in the process. I don't know what that will mean the next time there is a person who would cooperate because we don't want to go so far in the opposite direction that we're punitively restricting movement of people unnecessarily. This balance is going to be very tough, and I think the best way to handle it is to try to learn our lessons as we go forward, but also to be transparent about the decisions that we're making when we're making them and what we learn in the process. I appreciate that you've given me so much time today to be able to try to present the larger context here.

Senator HARKIN. I appreciate that, and we thank you all, and we'll move on to our next panel. I just want to let you know that we will be looking at—we, I say “we” collectively, Senators and this subcommittee and others, I'm sure, taking a look at—any legal things that we need to have changed here to provide a legal structure for CDC to be able to do this. We look forward to working with you on looking at that legal structure, what needs to be changed.

Dr. GERBERDING. Thank you. That would be very helpful. Thank you.

Senator HARKIN. We'll do that. Thank you very much, Dr. Gerberding. Dr. Fauci, Ms. Spero, thank you very much.

Now we'll move to our second panel. On our second panel we have Mr. Andrew Speaker, an attorney with the Speaker Law Firm of Atlanta, Georgia. Obviously, I don't think I need to say anything more than that. He is obviously the person who, the focus of this hearing today, not so much he himself, but the circumstances surrounding this and the possible threat to public health, as we just heard from our first panel.

Then we have Dr. Steven Katkowsky, the Director of the Department of Health and Wellness at the Fulton County, Georgia, Department of Health.

Then we have Mr.—Dr. Nils Daulaire, the President and CEO of the Global Health Council. Prior to assuming this position, Dr. Daulaire was the Deputy Assistant Administrator for Policy, as well as Senior International Health Adviser, at USAID.

So we have Dr. Katkowsky here and of course Dr. Daulaire, and on the phone we have Mr. Andrew Speaker. Mr. Speaker, I know you're at somewhat of a disadvantage because you're not here today. I had hoped to, as I said, have set up a visual connection, but somehow that couldn't get done with the National Jewish Hospital in Denver. I'm sorry that you missed most of the first panelists' testimony. I think you heard some of our questioning.

But again, Mr. Speaker—and you obviously did not hear my opening statement, but for your information this subcommittee is the committee that basically funds NIH and the Centers for Disease Control and other institutions of health. And we have been in-

strumental in the past few years in providing funding for CDC in Atlanta—of course, you're from Atlanta; you're well aware of that—and for the NIH in strengthening our public health system here in America.

There is great concern, Mr. Speaker, about your movements abroad, leaving this country, going abroad and coming back, and that—and perhaps exposing others to a very extreme form of the TB bacteria, I guess I would say. It's not a virus; a bacteria.

Again, I want you to know we all sympathize with your situation and the fact that you do have this, and we pray for your recovery and we hope that the good people at National Jewish will be able to treat you adequately and get you through this period of time and get you back to a state of good health. You are at one of the best facilities in the world for that right now.

So I just want you to know that you are not without some sympathy and understanding on the part of this subcommittee. However, we do have another responsibility and that is to the public and to the public health. Again, that's why we are concerned about the procedures, processes, laws, things that we need to do to protect public health in the future. So I hope you understand that.

With that, I would just turn it over to you for any statement that you might have to this subcommittee, and if you would then be responsive to any questions the subcommittee might have. So Mr. Speaker, again welcome, at least telephonically, and again you have our best wishes for a full and fast recovery.

STATEMENT OF ANDREW SPEAKER, SPEAKER LAW FIRM, ATLANTA, GEORGIA

Mr. SPEAKER. Thank you, sir.

First of all, as you know, I'm here at your leisure. Anything you care to ask me, please feel free. I'm going to try and—unfortunately, I didn't hear everything. A few of the points that were made I'm going to try and go over, because I know Ms. Gerberding just said that it made her sad and the covenant of trust, but a few of the things you were told are simply not accurate.

She mentioned that there was a test in March was the last smear-negative test I had. I actually—since January when this came out, I have fully cooperated with everything anyone has asked me to do, whether it's taking a test, an MRI, an X-ray, anything along the way. When it was finally verified that I had TB, I believe it was early to mid-April, Fulton County called me up and asked me to come down. I cleared my schedule that afternoon, went down, got another smear test, which turned up negative, got more blood work.

Actually on that day—I'm sorry I don't have the exact date—but I spoke with an official from the CDC, conveyed my plans about the wedding. They did know about this. This wasn't something hidden. This was something that was out in the open, that numerous officials of the CDC, at the county level, my doctors, everyone knew about.

I started treatment at that point. CDC started doing—and cut me off at any time. I'm just going to speak.

Senator HARKIN. Go ahead.

Mr. SPEAKER. CDC at that time—I had a bronchoscopy and they started doing cultures. So when I had the much-discussed meeting on May 10th, at that point on May 10 CDC was aware of my travel plans. While it may not have been communicated up the chain of command, that's not something I'm really privy to. But I do know that not just my father-in-law, but numerous people at CDC knew of the travel plans. It was CDC who was doing the testing, who helped come back with the fact that I had MDR TB. That was by the date of May 10. I'm not sure how far in advance they knew that, but I know at that meeting on May 10 I was made aware.

Right now there's this—I understand people's utter fear with this because they hear on the news and on TV that with the TB, even if I'm smear-negative, I'm not highly contagious, but there's still a chance. I hope that you and the committee understand that when I sat there on May 10 with MDR TB it was my father, my father-in-law, my bride to be, my doctor, and the health official; none of us were wearing masks.

I was repeatedly told that I was not contagious, not that I was partly contagious, but that I was not contagious, that I was not a threat to anyone. I was walking around, doing my job. As far as I knew from my medical advice—and I don't think anyone's going to get up in front of you today and tell you otherwise—I was clearly told I was not contagious. They were letting me walk around and go about my business.

So I look to the people who I believe I should trust to tell me whether or not I'm a threat to those around me, and they told me I wasn't. No one ever told me I was a threat to my wife or my daughter. If they had of, obviously if I got to that meeting and they said, you have MDR TB, either my father-in-law would have said, you've got to be careful and stay away from my daughter and my granddaughter because you could get them sick, my dad would not have let me be around my mother. I just myself wouldn't have been around my wife or my daughter and taken that risk that I could give them this. I don't want this and I wouldn't have wanted to give it to somebody else.

But as I said, CDC knew that I had it. They were aware that I was going on my travels. Yes, I was told that Fulton County would prefer I not travel, but I was also told I was not contagious. I was told I was not a threat to anyone. I was told there was no need to sequester me. With that information—I'm sitting here in quarantine and isolation, and yet I'm still smear-negative.

So maybe they should have told me before, but that's—I'm not a doctor. They should have told me 2 weeks ago: Look, you're a threat to your family and those around you; get out to Denver. But at that meeting we knew it would take 2 to 3 weeks to find out what type of, I believe it's MIC, it's my minimum resistance, what my—which drugs I was susceptible to. It would take a few weeks to get a bed in Denver. As long as I'm walking around and I'm not a threat to anyone, why not go on my honeymoon for the next 2 to 3 weeks instead of just sitting at work and going to court and doing everything else?

Senator HARKIN. Well, Mr. Speaker, again this is information again I wish I'd had prior to Dr. Gerberding leaving. She had to

leave to go over to the House side. But I intend to call her back now, or at least I will keep her on the record on this.

You are saying that on May 10 that you were in a meeting with people from both the Fulton County, but there were people there from CDC? You're certain of that?

Mr. SPEAKER. What I'm saying, sir, is that—and by default, yes, my father-in-law was there, but he was not acting in a CDC capacity. CDC was doing resistance testing and was communicating that to Fulton County, who I had the meeting with. So they were aware of the drug resistance. CDC had my culture and they were doing the resistance testing on it, which they helped pass on to Fulton County. So they knew that I was MDR on the 10, and they knew that I was traveling. They knew I was traveling because I told that to the CDC official when I went to Fulton County weeks before this.

Senator HARKIN. See, Mr. Speaker, what I have learned is—two questions here. I was told earlier, and I went at length on this, that the Fulton County officials—and we have Dr. Katkowsky here and we'll ask him about that—that CDC was notified on May 18 that you had an MDR strain. It is your contention that CDC actually knew about this before that?

Mr. SPEAKER. There were conversations back and forth between my doctors, the doctors out here in Denver, CDC, Fulton County. They were all discussing this because of the fact that there was resistance, and to set up and talking about getting me out to Denver. All this was being discussed before that meeting on the 10th and that's how they knew they would take weeks to find out exactly what was left that I was susceptible to. The CDC was doing those drug resistance tests. So to say that they didn't know when they're the ones who were coming up with the resistance is ridiculous.

Senator HARKIN. So before this meeting on May 10, you had already been in conversations with your doctors and with health officials and with people out at National Jewish Hospital?

Mr. SPEAKER. Yes, sir, because the meeting on the 10th was called because I was already on—they had asked me to go on your standard, their standard four drugs they treat TB with. I had been on them for a few weeks, and they called the meeting because they said: Look, you're resistant to these, so we need to go—we might as well take you off of them because they're not doing any good and let's talk about your treatment plan and what drugs are left. That was the purpose of the meeting, to talk about what my future treatment would be, because they knew that I was resistant and now we need to figure out the next step. That next step was trying to get a bed in Denver and figuring out what my resistance would be.

But I'm still—mind you, I'm still walking around this whole time, going to court, and no one has said a single word to me, including at that meeting, that I am a threat to anyone. I want people to understand that I'm not walking around knowing that I have TB and not seeking treatment. I am following all the guidelines of treatment that my doctors are telling me at that time. I was on medication, and they're the ones who took me off because they knew it wasn't doing any good.

Senator HARKIN. I see. Now, one last thing I think you mentioned that I picked up I made a note on and I want to make sure that I'm correct on this. Did you say you contacted CDC in April or did your doctor contact CDC?

Mr. SPEAKER. Sir, well, Fulton County—my doctors as part of protocol contacted Fulton County and let them know that I had TB. So Fulton County called me and I went down to Fulton County and met with a CDC official who was working with Fulton County and who interviewed me. I told him about my wedding plans. I told him about my travel plans. At that time my health provider had already put me on the standard four-drug regimen a few days before.

So they took another sputum test at that time, which was some time I think early mid-April, which came back negative. They said, okay, continue your treatment, because when I was speaking to Fulton County at that time we didn't know it was resistant, and you get your treatment every 30 days and that 30 days would have elapsed while I was in Europe. So I told them that they needed to give me an extra 30 days before I left so I didn't run out while I was in Europe on my honeymoon, so I could keep taking my medication. This was before, you know, they took me off of it because I was resistant.

So to claim that—everyone knew I was going. I didn't go running off or hide from people. It's a complete fallacy and it's a lie.

Senator HARKIN. Well, Mr. Speaker, this is interesting news. We have Dr. Katkowsky here and we'll go over with him about the Fulton County. We'll move ahead on that right now. Please stay on the line. I will come back to you, but I want you to hear their testimony, Dr. Katkowsky and Dr. Daulaire, and we'll be back to you. So stay on the line with us.

Now we'll turn to Dr. Katkowsky, director of the Department of Health and Wellness at Fulton County, Georgia, Department of Health. Dr. Katkowsky, welcome to the committee and please go ahead and proceed and fill us in on the circumstances as you know them.

STATEMENT OF STEVEN KATKOWSKY, M.D., DIRECTOR, DEPARTMENT OF HEALTH AND WELLNESS, FULTON COUNTY, GEORGIA

Dr. KATKOWSKY. Good morning and thank you, Chairman Harkin. I appreciate the opportunity to appear before you today.

Senator HARKIN. Would you pull the mike in a little bit closer to you there, Dr. Katkowsky.

Dr. KATKOWSKY. Is that better?

Senator HARKIN. That's fine, thank you.

Dr. KATKOWSKY. I was just thanking you for the opportunity to appear here today.

Specifically, lots of things that have been discussed both by the first panel session and just now by Mr. Speaker leave some question as to perhaps the time line and what everybody remembers as the time line and what everybody remembers as the time line for what happened, what didn't happen, what might have been communicated.

Mr. Speaker was correct, he was referred to the Fulton County Health Department on April 23 because of a positive culture for TB. He was seen in our department on April 25 in our TB clinic.

The physician that saw Mr. Speaker was also a CDC physician who is an expert in TB. He was not working as a representative of the CDC. He was working for the Department of Health and Wellness in Fulton County. So there really are a couple of parallels.

Senator HARKIN. So he was not a CDC employee, or was he?

Dr. KATKOWSKY. He was a CDC employee, but he was working at a local health department in a TB clinic. I think perhaps that's where some of the question arises as to what did CDC know and when did they know it. I think the greater question is what did they know, when did they know it, and from whom did they know it.

Yes, Mr. Speaker was put on the standard regimen of drugs, and with subsequent testing, yes, he was smear-negative, as Dr. Gerberding said. But he remained culture-positive.

Now, the local health department does not have the means to be able to do the kind of specialized tests to determine, number one, resistance to the strain of TB; number two, the degree of resistance to a strain of TB. Our initial TB tests are conducted by the State public health laboratory. As Dr. Gerberding said, the CDC has the laboratory ability to then test for sensitivity, resistance, and so on to the different standard anti-TB drugs.

This strain of TB proved to be resistant. In a meeting with Mr. Speaker, with his physicians and some family members, that took place on May 10, he was informed officially that he had MDR, or multi-drug-resistant, TB. That in and of itself from a health perspective is cause for concern. The cause for concern is brought about because drug-resistant tuberculosis to any degree is much more difficult to treat. The treatment itself takes longer.

The recommendation was made, as Mr. Speaker says, to seek treatment in Denver, Colorado, at a specialty facility. So a lot of these things are coming together, but the juxtaposition of them I think really requires further explanation.

Upon making his status known to him, the other piece of information that was transmitted was: No, you should not travel. The question that's been asked over and over again, was Mr. Speaker prohibited from traveling, was he ordered not to travel, and the answer to that was no. The local health department does not have the authority to prohibit or order somebody not to travel. In Georgia our role is to be able to go to the courts to seek an order to compel either treatment, isolation, or restriction on travel.

We had consulted with the Fulton County attorney's office and asked them what action might be available. Unfortunately, as you've heard before this morning, the way a lot of the laws are written is action can't be taken until a violation has occurred. In other words, we can't be proactive. I can't look at somebody and say they might rob a bank. I have to wait until they rob a bank to then be able to take the necessary legal action.

Well, in this case, as Mr. Speaker clearly points out, he did not refuse treatment. He did not refuse to be tested. He had also not violated the medical directive to not travel. So we found ourselves in a catch-22 where the law provides for action to be taken after there's a violation, but not before in a preemptive way that would have allowed us to be able to prepare.

One of the questions that I know the committee has asked this morning was what could have been done or would have been done differently. I think had the local health department been in a position where the laws would have allowed the department to be anticipatory rather than reactionary—and by that I mean we could have, had the law allowed, issued a request to the courts, have an isolation order or have a restriction on travel order issued, and then have an immediate or within 72 hours a hearing for the patient to be able to come forward, present their information, and then have the court decide whether or not that order needs to remain in effect, while balancing the patient's rights with the rights of the rest of the population.

One of the things that was a great concern, and as a public health official I must tell you the thing that was a great concern, was Mr. Speaker's health, his well-being, the treatment he would and could receive, as well as the health and well-being of the population.

Senator HARKIN. Well, Dr. Katkowsky, again Mr. Speaker—I took my notes here—that on May 10 he said everyone was aware of his travel plans, he had not hidden them, that CDC was present, I assume in this person that you spoke about, this physician that is at your Fulton County health facility, he was made aware of the MDR TB, but no one, he said, was wearing masks. He was told that he was not contagious. He was not told to avoid people.

You heard what Mr. Speaker said. So in that framework, it would seem to me that the average person would say, well, okay, I have this thing, but if I'm not contagious and all these people around me, they know about my travel plans, but no one said that he shouldn't do this. He was told he was not contagious.

Is that your recollection?

Dr. KATKOWSKY. No, sir. First of all, I was not in the meeting, but the patient's chart indicates that he was told he was not highly contagious. As Dr. Gerberding pointed out earlier, that somebody who is smear-negative but culture-positive is still able to transmit tuberculosis. As a matter of fact, about 17 percent of all the cases that we see are transmitted by people who are smear-negative.

The other piece of information is that, yes, we knew of his plans to travel; the plan that we knew of was for Mr. Speaker to travel outside the United States on May 14. We then, in this case incorrectly, assumed that we had at least 4 days to be able to work up a plan, be able to put plans in place, and that would have included referral to Denver, Colorado.

Yet what we found out was Mr. Speaker moved up his travel date, was not available, could not be reached, and the whole question of whether or not we could have compliance at that point and was it safe for him to travel could not even be addressed because at that time he was out of the country.

Senator HARKIN. I'm going to get back to Mr. Speaker on this. He is still listening. Before I do, I'm going to go to Dr. Daulaire, though. Dr. Daulaire—"Doe-LARE," I'm sorry; I mispronounced that—President and CEO of Global Health Council.

Dr. Daulaire, welcome to the committee. Please give us the benefit of your insight into this.

**STATEMENT OF NILS DAULAIRE, M.D., M.P.H., PRESIDENT AND CHIEF
EXECUTIVE OFFICER, GLOBAL HEALTH COUNCIL**

Dr. DAULAIRE. Thank you very much, Mr. Chairman.

Senator HARKIN. Pull that mike in a little bit.

Dr. DAULAIRE. Right. I would request that my full written statement be submitted for the record.

Let me just change the frame here for a moment if I can. We've been talking about, if you will—it's summertime—a swimmer and a single wave, and perhaps a failure at a life guard station. What I'd like to talk about is the ocean because there are a lot more waves where this one came from and a tide that's coming in.

Frankly, as long as the tide of global infectious diseases broadly and MDR and XDR TB in particular continue to rise, quarantine and border controls will never adequately protect Americans. So I think it's very important to recognize that we need to look outside our borders as well as at our border protections if we're going to be fully addressing these issues.

Now, the Global Health Council, the organization I lead, represents health professionals and service organizations working in more than 100 countries. We know this issue up close and personal and I've dealt with it for three decades myself. We recognize, as Dr. Fauci said, that one-third of humans on the face of the Earth, 2 billion or more people, are already infected with the TB bacillus, that 8 million of them will become sick with TB this year, and that somewhere between 1.6 and 2 million will die this year.

But what I think we are at risk of neglecting is the fact that this is really a moving train. Eight years ago the global health community raised an alarm about the growing threat of multi-drug-resistant TB. It was new on the horizon at that point, and the fact that there were now outbreaks of cases around the world, again 8 years ago in 1999, that indicated that there were now a growing number of TB cases that did not respond to first-line drugs, was a cause of real concern.

Today we're dealing with extensively drug-resistant TB and the estimate today is that there are somewhere in the vicinity of half a million MDR TB cases in the world and that about 10 percent of those, about 50,000 of them, are XDR TB cases. So 50,000 people just like Mr. Speaker around the world that pose a public health risk to all of us.

What I want to make sure we address today and going into the future is that 8 years from now that we're not having a hearing that talks about TDR, totally drug-resistant TB, because that's the next step along this chain unless we get control of the situation globally, not just at our borders and within the United States.

Now, I have enormous sympathy for Mr. Speaker and the condition that he's under because, frankly, as a physician myself I would sooner have a diagnosis of cancer than a diagnosis of XDR TB. The cure rate for XDR TB is under 30 percent at this point and fewer than 50 percent of people with XDR TB in active cases survive 5 years. So it's a very dangerous situation to be in. On top of that, someone with cancer isn't at risk of spreading it to other people, as people with TB are.

This is certainly a national security issue and I'm glad that this committee has raised that as a concern. But it's not about terror-

ists or the idea of people voluntarily infecting themselves. We have literally millions of people around the world crossing borders every day. Many of them are infected, whether it's with TB in one of these variants or other infectious diseases. What we need to do is to recognize that unless we address the problems of these diseases, particularly TB but others as well, at their source, which is in the world's poor communities around the world, that no walls that we can build can possibly be high enough to protect the American population.

That's the nature of today's world and the best guess right now is that Mr. Speaker himself contracted his XDR TB traveling in Peru or possibly in Vietnam. So we are a Nation of travelers and we're a Nation of immigrants, and we are not an island in the world. In a globalized world, all of us, rich countries and poor countries alike, paddle in the same microbial sea.

So what we need to recognize is that most XDR and MDR TB cases are unknown, unrecognized. It's just by chance that Mr. Speaker's was identified when he had his rib injury and got X-rayed. And we probably have dozens, possibly hundreds, of people traveling internationally on airplanes every day who have infections that could be at risk for other people.

We need to get into the communities where this is spreading rapidly and institute good controls. Now, it's not principally about a technological fix. Yes, new drugs that will treat TB more quickly or that will work against MDR and XDR TB are very—going to be very important tools, and new vaccines, as Dr. Fauci talked about, that work effectively for adult pulmonary TB are very important. But right now we have the opportunity to go and to work with countries around the world in terms of their TB control programs in their own communities.

XDR and MDR TB are results of failures of basic TB control programs. There's examples of successes. Indonesia and the Philippines have done good programs and in fact China as well have greatly reduced the emergence of new and more dangerous forms. So this is very doable.

I would congratulate the Senate on the introduction of two bills, one domestic and one international, for addressing TB. Senator Brown's leadership on this issue has been really laudatory and it goes back to his time in the House of Representatives.

But the CDC has had, as Dr. Gerberding said, flat-line funding for the last 10 years. It's a real decrease in terms of actual programs on the ground. Local health departments are hurting. The investments that are being carried out by—

Senator HARKIN. The time. There's two votes on the floor.

PREPARED STATEMENT

Dr. DAULAIRE. I'll wrap up.

The investments carried out by NIH are dwarfed by the investments of one single foundation, the Gates Foundation. I think the United States Government needs to do more to protect our citizens, our children, and our grandchildren.

Thank you.

Senator HARKIN. Thank you very much, Mr. Daulaire.

[The statement follows:]

PREPARED STATEMENT OF DR. NILS DAULAIRE

Chairman Harkin, ranking member Specter and members of the subcommittee, thank you for inviting me to testify before you today on “Cracks in the System—An Examination of One Tuberculosis Patient’s International Public Health Threat.” I am Dr. Nils Daulaire, President and CEO of the Global Health Council, the world’s largest membership alliance of health professionals and service organizations working to save lives and improve health throughout the world.

Before I begin my remarks, let me thank you, Chairman Harkin, for your leadership not only on domestic health issues, but also recognizing that the health of our brothers and sisters around the world is also of priority. Your commitment to shoring up bioterrorism resources and capabilities has reinforced the link between health and national security. Senator Specter, your commitment on HIV/AIDS is much appreciated as this disease continues to wreak havoc on communities around the globe. On behalf of the Council’s 350 member organizations working in over 100 countries across the globe, and the millions whose lives are improved by U.S. Government investments, we thank you.

The Global Health Council’s members include non-profit organizations, schools of public health and medicine, research institutions, associations, foundations, businesses and concerned global citizens who work in global health—delivering programs, building capacity, developing new tools and technologies and evaluating impact to improve health among the poor of the developing world. Our members work in a wide array of areas, including child and maternal health, family planning, HIV/AIDS, other infectious diseases, water and sanitation, primary health care and health systems strengthening. The members of the Council share a commitment to alleviating the great health disparities that affect the world’s most vulnerable people. The Council serves its members and the broader community of global health stakeholders by making sure they have the information and resources they need to fulfill this commitment and by serving as their collective voice.

It has been my privilege to be part of the global health movement for over 30 years, and much of my career has been spent as a physician and program manager in some of the world’s poorest countries—most of them places where TB is widespread and where control is challenging. Working in countries such as Nepal, Mali and Haiti, I have had the good fortune to participate in the development and front-line delivery of a number of important basic health interventions. I have also had the honor of serving in government as a senior policy advisor in USAID. My remarks today derive from these different perspectives and experiences, as well as the evidence and experience of the Council’s membership.

No matter how informed or how prepared we think we are, like many of you, I was caught off guard by last week’s news of an individual—an American, no less—who traveled around the world and back with a highly dangerous form of tuberculosis. As we have seen in the media and heard from public officials, there were a number of missed opportunities along this man’s itinerary that could have caused serious harm to others. We dodged a bullet on this one. It appears that the impact of this one man’s travel will be minimal. But, the question of “What if?” certainly lingers. What if this happens again? What if the patient is more contagious next time? How can we ensure that we protect those both in this country and around the world from a deadly infection? This is a fundamental tenet of public health.

Please realize that every lesson we need to learn about prevention and protecting the public’s health is present in the current story of this American traveler. This was an educated man—a lawyer. His immediate family works at the world’s leading public health prevention agency—education and awareness should have been no issue. He accessed the medical system and consulted with providers. Yet, somehow, we sit before you today describing a “crack,” as the hearing’s title implies, in the system. As this case could certainly be considered one of national security, let me assure you, there is no border control possible that will stop infectious diseases from entering our country. We must address infectious health threats at their origin as well as our borders and across our States.

Tuberculosis (TB) represents the classic public health challenge. It is a communicable disease, perpetuated by and reinforcing poverty in resource-poor settings; it spreads due to crowded conditions and poor sanitation. TB taxes and, through its spread, exposes weaknesses in every part of the health system from surveillance to labs and from diagnostics to the health workers that ensure that the established treatment strategy is appropriately delivered. In short, TB is a snapshot of the broader health system and global health portfolio, what’s working and what is not.

There was a time when TB was a major public health challenge in the United States, but with the advent of then-effective medicines in the 1940s, rates began to decline and TB became an uncommon disease in this country. We all remember the

TB test of our school days, carried out by a simple pinprick on our forearms as a part of our scheduled medical check-ups. This vigilance was a sign that the health system respected the potential threat of this airborne bacteria and the importance of preventing its spread by promptly identifying and then treating those who had been infected. However, in the 1970s and 80s, the country let its guard down by decreasing investments in basic TB control programs. As a result, TB rates began to rise.

Although TB is no longer considered to be a major public health threat in the United States, it still infected almost 14,000 people in 2006. This is only a fraction of the global TB burden which is characterized by nearly 9 million new active cases each year and 2 million deaths. Eighty percent of active TB cases are concentrated in only 22 countries; an epidemic dominated in the prison populations throughout eastern Europe, in overcrowded villages and slums in Asia and among HIV-positive individuals throughout sub-Saharan Africa.

There has been progress. China is an example of an exemplary success story in TB control. In 1991, China launched a 10 year effort to reduce TB in 13 of its 31 provinces. The strategy was to implement the DOTS strategy (directly observed therapy short-course) using village doctors with basic training as the primary provider involved in surveillance, diagnosis and treatment. The village doctors referred suspected cases to dispensaries where diagnosis could be done and the followed up with treatment. The outcomes were: treating 1.5 million people, eliminating 836,000 cases of pulmonary TB, a 95 percent cure rate for new cases, a 90 percent cure rate among unsuccessfully treated previous cases, a 37 percent decline in the number of people with TB and preventing 30,000 TB cases per year. The costs were \$130 million total with each successful treatment costing less than \$100/person. The program has had a very high rate of economic return. This effort represents classic public health, a basic health systems approach—absolutely necessary and yet perpetually underfunded.

As you know, TB is a disease caused by the *Mycobacterium tuberculosis* bacteria. The infection usually attacks the lungs and manifests as weakness and fatigue, chills, loss of appetite and bad coughing fits. Two billion people—one-third of the global population—are infected with TB. For most, it will remain latent, a silent hitchhiker, causing no symptoms and not a risk for infecting others. However, 1 in 10 will eventually manifest the disease. TB is diagnosed using a blood or tuberculin skin test or, in the developing world, an old fashioned sputum smear and examination under a microscope—a technology employed in the 1880s and still used today. Two lines of drug treatment currently exist for TB. These treatments are most often delivered via the DOTS strategy—Directly Observed Therapy short-course. Of course, “short course” in TB means 6 to 9 months of carefully monitored treatment with multiple drugs. So, while it is relatively inexpensive—\$20 or so in drug costs over the full course—it requires perseverance and good management on the part of the health system.

As with other communicable vectors, TB is a smart bug. Over time, given the opportunity caused by breaks in treatment, it grows resistant to available drugs, requiring the use of second-line drugs and longer treatment regimens. At this point, one experiences multi-drug resistant (MDR) TB. This resistance is expedited when TB patients prematurely halt their treatment course, mistaking feeling better for having rid themselves of the infection itself. The frightening news of late has been the emergence of the extensively resistant form of TB (XDR-TB) that responds to neither first- nor second-line drugs. In fact, treatment options are incredibly limited and what is available is expensive, costing in excess of \$7,000 and running a treatment course upward of 24 months. This assumes, however, that patients are diagnosed, are able to access treatment and don’t succumb almost immediately to XDR-TB as many have in South Africa.

Dr. Gerberding has shared the current epidemiological update of MDR and extensively-drug resistant (XDR) TB. I will only reinforce her summary to say that the current situation with MDR-TB and, most recently XDR-TB, demonstrates clearly that our global public health infrastructure is not working. XDR-TB is a 100 percent man-made phenomenon, resulting from unsustained investments in basic public health.

The 2006 news out of KwaZulu Natal teaches us important lessons. First, the impact of infectious disease can be rapid—too rapid for an unprepared health system. Of the 53 individuals first identified to be infected, 52 died—in an average of 16 days. There is a real human element to this. Health systems, through their workers, must be in touch with their patients. They must communicate and ensure that patients are seeking appropriate treatment. Second, our intelligence is only as good as our intelligence gathering systems. Africa has 25 major laboratories that are able to detect drug resistance; 19 of those labs are located in South Africa. So, we, in

truth, have no idea of the extent of the XDR situation throughout Africa or other parts of the world. We only know about South Africa because that is where the capacity exists. Finally, even once we identified XDR-TB, we had no way to adequately treat it, demonstrating that research and development of new drugs and program delivery must run on parallel tracks with simultaneous investment.

Allow me to share this analogy with you to stress the importance and potential impact of the current TB situation. Our cars have dashboards with a series of icons that light up when something in the car's system needs attention. So, when the "check engine" light comes on, we know we need to tend to the engine before a larger systems failure occurs. We should consider the current TB situation to be a blinking light on the dashboard of our public health system. Something is wrong. Something is not working. It needs attention or we will, no doubt, experience larger systems failures that will cost not only money, but perhaps millions of lives over time.

I encourage the committee to direct its attention to the current threat of MDR and XDR-TB. But, I caution you to not just focus on just this single disease as it does not occur in isolation, particularly in the developing world. I further caution you look beyond the immediate situation—one that has been brewing for some time now, but was just recently brought to mainstream attention by the recent news story out of Atlanta. You'll recall West Nile Virus a few years back. With that threat, the government generously supplemented Federal, State, and local health budgets with resources for the virus. Since 1999, we have spent well over \$100 million for a disease that took fewer than 1,000 lives total. Yet, the health system grew no more prepared to respond to future threats and other public health priorities starved, continuing to cost health and lives.

Instead of attempting to tend to the Nation's health one issue—no, one emergency—at a time, I hope I can persuade you to take a comprehensive systems approach to support public health here and in the world's poorest countries so that if, and in the case of an increasing number of infectious diseases, when these situations occur we have the surveillance systems that recognize them early, we have the laboratory capacity to accurately diagnose, we have a healthy technology pipeline that makes diagnostic tools and treatments available quickly and consistently, the health workforce to deliver the interventions and manage the programs and the monitoring and evaluation systems to know how we've done and how we can do better. Like our car engine, these pieces need to work together: a system. U.S. investments in a sustainable response, in cooperation with the World Health Organization and its developing capacity to share information on global health events quickly and with clear guidance to member states, will benefit everyone no matter where they live or travel.

I also encourage the committee to recognize that today we are discussing TB. Tomorrow it will be something else. That is nature of health in a globalized and interconnected world. I cannot overstress the need to think comprehensively and long-term.

The MDR and XDR-TB situation before us is serious. However, the good news for TB is three-fold. First, it does occur in the United States and not only overseas, making it difficult for our policymakers and program managers to ignore. As a result, State and local public health departments include TB in their portfolios and are largely able to identify the disease and respond. Second, TB shares center stage along with AIDS and malaria as one of the most visible public health challenges facing the world today. Undoubtedly, the last decade has represented a period of unprecedented and unparalleled attention and resource mobilization for the overall global health agenda, with much of the attention concentrated in AIDS and, more recently, malaria. Because of the close links, TB shares in that attention and those resources and hopefully comparable investments specific to TB are soon to follow. And, finally, although we need to shore up the technology pipeline by investing in research and development for new tools and treatments, we can make great progress with what we currently have available. Basic TB control demonstrates what is possible when provided attention and resources.

Mr. Chairman, there are three immediate steps Congress can take to address the threat of MDR and XDR-TB:

1. Continue and enhance funding for basic global health programming through the Centers for Disease Control and Prevention, for global health research at the National Institutes for Health and technical guidance through the U.S. Agency for International Development (USAID) so that no one is left to fight this evolving disease without prompt diagnosis, effective medications and treatment support. Domestic and global TB investments have stagnated over recent years, threatening a repeat of what we experienced in the 1970s and 80s when we assumed that declining incidence rates meant that investments could decline as well. Let us recognize and support the very good work of the CDC and the NIH that provide the leadership

and content for our domestic and global health efforts. Level funding of bilateral programs and proposed cuts to contributions to the Global Fund to Fight AIDS, TB and Malaria in the coming fiscal year simply will not stand. A reduction in investments will cost us lives.

2. Legislatively, there are a number of bills that address both the TB situation and broader systems issues. Support for the Comprehensive TB Elimination Act of 2007 and the Stop TB Act of 2007 is needed now. In addition, support for innovative financing and incentivizing private industry engagement through market activities outlined in the Vaccines for the New Millennium Act is also warranted. Finally, the global health community urges you to support the African Health Capacity Investment Act to assist countries in sub-Saharan Africa—a region where some countries have as few as 20 health care professionals per 100,000 people—in the efforts to achieve internationally recognized goals in the treatment and prevention of HIV/AIDS and other major diseases, including TB, by improving human health care capacity and improving retention of medical health professionals in sub-Saharan Africa. It must be noted, however, that the health care worker shortage is global and not just confined to sub-Saharan Africa. A comprehensive response to this issue is needed.

3. Support the public health investments needed to make sure the United States is fully integrated into the global surveillance and events management and response systems being developed at the WHO as the International Health Regulations go into effect this summer. In addition to making sure our national monitoring and response system is in place, as my colleagues have elaborated, the Global Health Council's perspective is that the health of the world knows no borders. We cannot protect the health of the American people in isolation, but only by sharing information, resources and a transparent emergency response system with all other countries.

Yes, tuberculosis is a disease of the poor and, often, the uneducated. However, this case dispels every possible stigma one could attach to this disease. It proves that a global outbreak is just a flight away and it may—as our traveler did—make a pit-stop in Greece, Prague, Italy, and Canada—covering the world in a week. If it could happen to this gentleman, it could happen to anyone. Let us not treat just this individual situation or this individual because he is an American. Recognize what this case represents. The solutions are not just in this room. They are at local levels. Yes, the Fulton County Health Department, but also the district level in Southeast Asia where it appears he may have contracted the initial infection.

We cannot resolve the TB situation “here” without resolving it “there.” When it comes to health, there is no “them,” only “us.” Fixing the cracks, if that is possible, requires a global solution at the level of basic public health systems in the poorest parts of the world.

Senator HARKIN. Mr. Speaker, there's two votes on the Senate floor that I have to go tend to right now, so I have to adjourn the hearing. I just have a couple of questions. Do you have any idea where you contracted this TB?

Mr. SPEAKER. Well, sir, there's two options. I was in Vietnam with the Rotary Club last year and we went around to orphanages and hospitals helping out for about 5 weeks, and it could have been there. Or it could have been, I was in Peru about 6 years ago and it could have been at that point.

Senator HARKIN. I see. Well, you're unfortunate in that you've got it. It was again a fortunate circumstance where you had this rib problem and got in and got diagnosed, as I understand it, at an early stage.

I'm not trying—it's not my intent here to get into a he-said-she-said type of situation between you and Fulton County and Dr. Gerberding. But what I am trying to do is to ferret out just how this process worked, what happened, what was the misinformation, so that we don't have this same kind of thing occurring again.

One last question I have for you, Mr. Speaker, is why did you move up your date from May 14 to May 12?

Mr. SPEAKER. Well, you've got to understand at that time I was trying to change jobs. My family, a lot of my family had already

gone over. I was just told that I was going to have my right upper lung taken out likely, that I was going to have 2 years of treatment where I'd have daily IV injections, if not every other day. So I wasn't going to go anywhere for probably the next 2 years because I'd have to have officials coming up for the IVs every day.

My wife was busy with—she was in law school and she had a trial clinic on the weekend. I wasn't sleeping. My wife said: Look, honey, everybody's going over. I had already taken her parents to leave over there. She said: Why don't you just go on over; you know, once you get over there you're not going to be worried about things, you're not going to be stressed about things, and when we come back we'll worry about it then.

Again, why should I be worried if Fulton County never addressed it head-on, or at least I didn't hear it. But I was clearly told word for word I was not contagious and I was not a threat to anyone, that there was no need for me to be sequestered when I got out to Denver, because I wasn't contagious.

I just hope that's—and there are some other—I hope we do get to address it again because I really would love the opportunity to discuss what happened in Rome. I think there's an impression that we just fled, but when we talked to the CDC we immediately ended our trip. We were supposed to head to Florence on a train the next morning. They told us cancel, we need you to cancel your trip; we're going to call you tomorrow with your travel arrangements. We immediately cancelled our trip, got another night in our hotel, didn't get on the train, and said, okay, if that's so then it's time to go home.

The next day they called us and—I mean, we called them later that next night, and that's when they told us: We've looked at all the options, we've been in meetings all morning, we're not comfortable putting you on a plane and we're not—there's no funding. I don't know where this stuff about the health risk on the plane came from. That was never mentioned to us. It was just told that the CDC doesn't have any funding to put private individuals on planes. You know, there's \$7 million to have them sit there a year, but nothing to actually use them.

So I was told that the only option—that my father had been called earlier that day and told that he, and her father had been called earlier that day, and they had both been told the only option was for them to raise the money and get me home. And I was told that if I didn't come up with, their estimates were up to \$140,000, to get myself home, I would have to stay there and be treated.

I had been told before I left that the people in Atlanta couldn't handle this, this was above their heads with the surgery and treatment. If I didn't get to Denver—you know, I wasn't dying. I was walking around. I felt great. But when it came time to treat it, if they didn't use exactly the right drugs, if I lost any more drugs, I would lose my chance.

So they asked me to voluntarily check myself in, that the authorities were coming in the morning, and I could be stuck there indefinitely in the Italian hospital. I came home, because again I asked them, what's changed? When I left I was noncontagious and I wasn't a threat to anyone, and what's changed? Why are you leaving me here? I just wanted to get home.

I'm sorry for all the stress I've caused people, but I hope they understand where I was. I hope it changes the policy and I hope the way they handle things changes.

Senator HARKIN. Mr. Speaker, thank you. I believe that's hopefully the benefit of this hearing and what we found out, that we are going to change some procedures. I have real questions also about the aircraft and why it was not just sent over. The CDC uses its aircraft to fly Secretary Leavitt around from city to city all over the United States. You're telling me it couldn't have gone over to pick up a highly contagious—well, not highly contagious; he wasn't highly contagious. That's the wrong choice of words. But to pick up an individual that they knew about, to bring them back here.

I just don't understand that the CDC couldn't have done that. Now, they said, well, the aircraft didn't have an isolation unit. Well, then there's a matter of how many hours. Well, you flew from New York to Atlanta, Atlanta to Denver, on the CDC plane. That's at least 3 hours, 4 or 5, maybe 5 or 6 hours total there. I've got to believe from Rome to New York to Atlanta probably on a G3 probably wouldn't be much over 8 hours total flight time. The patient's health insurer coordinated the transportation of the patient to Denver using their air medical contractor. The CDC airplane was not utilized to transport the patient to Denver.

So I'm thinking that this answer I've heard does not hold a lot of water. It looks like there was some bureaucratic mismanagement here. But that's again what we want to get at. We want procedures and processes in place, plans done ahead, so that incidents like this can be handled expeditiously in the best interests of both the patient, the individual, but also the public at large. That's where this thing just fell apart.

Again, I intend to have CDC back up here again to go through this again with them and to make sure that we have—we put these processes in place.

So I think, Mr. Speaker, again you have our hopes and our prayers for a full recovery. I hope that you will again continue to let us, our committee, be in touch with you as we move ahead on this. We may have further questions as this thing moves ahead. But I think you've enlightened us greatly with your testimony here this morning.

I thank Dr. Katkowsky also. As I said, I'm not trying to get into who said what and that type of thing. We have plenty of documentations on the timeframes and what was said and that type of thing. But better just to get at this and get it fixed so that we can assure the public that this won't happen again. That's really what we want to try to do.

So again, Mr. Speaker, our hopes for a full recovery. Again, this committee through our staff may be in touch with you, I hope, at some time in the future, if that will be okay with you.

Mr. SPEAKER. I'm here at your leisure, sir.

Senator HARKIN. Well, thank you very much. We know about National Jewish. It is one of the finest institutions in the world for respiratory illnesses. You are at the best place in the world right now. I know of that. I can assure you of that. I've been out to National Jewish myself.

Mr. SPEAKER. Yes, sir.

Senator HARKIN. So you have the best facilities and the best doctors out there.

Thank you again, Mr. Speaker and Dr. Katkowsky, Dr. Daulaire.

CONCLUSION OF HEARING

Thank you very much for being here.

[Whereupon, at 12:11 p.m., Wednesday, June 6, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair].

